US3202085 (Prod: WR-ClinSearch, LLC)

Form: Participant Creation
Data signed: (b) (4) **09 Apr 2021 13:51:45**
Generated On: 09 Jun 2021 15:44:53

Participant ID   US3202085

mRNA-1273-P301 Completion Guidelines

US3202085

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	09 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SCRN

US3202085

Folder: Screening

Form: Demographics

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	39
Age Units	YEARS
Age (Derived)	39
Sex	Female ◯
	Male ●
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ●
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)

White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

Date of Informed Consent *(dd MMM yyyy)*	9 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

Protocol Version

- Amendment 1 ●
- Amendment 2 ○
- Amendment 3 ○
- Amendment 4 ○
- Amendment 5 ○

Was participant enrolled in the study?

- Yes ●
- No ○

If No, indicate reason for screen fail

- Withdrew Consent ○
- Inclusion/Exclusion ○
- Cohort Full ○
- Other ○

If reason for screen fail is Other, specify _____

Was this participant screened previously?

- Yes ○
- No ●

If Yes, previous participant number _____

Enrollment Trigger	1

Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4)   **13 Feb 2021 01:55:27**
Generated On: 09 Jun 2021 15:44:53

Did the participant meet all eligibility criteria?   Yes ●

No ○

US3202085
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **13 Feb 2021 01:55:27**
Generated On: 09 Jun 2021 15:44:53

Were any significant conditions reported?   Yes ⬤

                                                                              No ◯

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	27 SEP 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3202085

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **09 Apr 2021 15:47:15**

Generated On: 09 Jun 2021 15:44:53

Condition	MIGRAINES
Start date (dd MMM yyyy)	12 APR 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (3)

Data signed: ▮▮ (b) (4) ▮▮ **09 Apr 2021 15:47:15**

Generated On: 09 Jun 2021 15:44:53

Condition	DEPRESSION
Start date (dd MMM yyyy)	12 APR 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

US3202085

Folder: Screening

Form: Medical History (4)

Data signed: [(b) (4)] **09 Apr 2021 15:47:15**

Generated On: 09 Jun 2021 15:44:53

Condition	HYPERTHYROIDISM (GRAVE'S DISEASE)
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **09 Apr 2021 15:47:15**

Generated On: 09 Jun 2021 15:44:53

Condition	ALCOHOL ABUSE
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3202085

Folder: Screening

Form: Medical History (6)

Data signed: ▨ (b) (4) ▨ **09 Apr 2021 15:47:15**

Generated On: 09 Jun 2021 15:44:53

Condition	BOTOX FOR MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3202085

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	09 AUG 2020
Time of assessment *(00:00-23:59)*	09:06 (24 HR)
Vital Signs Date and Time (derived)	09 AUG 2020 09:06
Height *(xxx.x)*	168.0 cm
Weight *(xxx.x)*	94.8 kg
BMI *(xxx.x)*	33.58844 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202085

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

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.

US3202085

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:55:27

Generated On: 09 Jun 2021 15:44:53

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ● No ○	
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ○ No ●	
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ○ No ●	
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ○ No ●	
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ○ No ●	
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ○ No ●	
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ○ No ●	
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ○ No ●	
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ○ No ●	
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ○ No ●	
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ○ No ●	
Other	Yes ○ No ●	

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

US3202085

Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **13 Feb 2021 01:55:27**
Generated On: 09 Jun 2021 15:44:53

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3202085

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	09 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

US3202085

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

What was the date of randomization? *(dd MMM yyyy)*	09 AUG 2020
What was the participant's randomization number?	102379
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 ●

US3202085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **13 Feb 2021 01:55:27**
Generated On: 09 Jun 2021 15:44:53

Height	ND - Not Done
Weight	ND - Not Done

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	09 AUG 2020
Time of assessment *(00:00-23:59)*	09:06 (24 HR)
Vital Signs Date and Time (derived)	09 AUG 2020 09:06
Temperature *(xxx.x)*	37.3 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	09 AUG 2020
Time of assessment *(00:00-23:59)*	10:22 (24 HR)
Vital Signs Date and Time (derived)	09 AUG 2020 10:22
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG

US3202085

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Was the physical examination performed?   Yes ⬤

                                                                               No ◯

Date of examination *(dd MMM yyyy)*   09 AUG 2020

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

US3202085
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **13 Feb 2021 01:55:27**
Generated On: 09 Jun 2021 15:44:53

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)*	9 AUG 2020
What was the treatment time? *(00:00-23:59)*	9:40 (24 HR)
Treatment Date and Time (derived)	9 AUG 2020 9:40
Which arm was used to give treatment?	Left Arm ●
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3202085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	09 AUG 2020
Collection time *(00:00-23:59)*	09:10 (24 HR)
Collection date and time (derived)	09 AUG 2020 09:10

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Collection date *(dd MMM yyyy)*			09 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:13	09 AUG 2020 09:13
Nasopharyngeal Swab 2	No		

US3202085

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	09 AUG 2020 10:21
PC Open Date & Time	09 AUG 2020 10:00
PC Close Date & Time	09 AUG 2020 12:30

FDA-CBER-2022-1614-0441810

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	09 AUG 2020 13:27
PC Open Date & Time	09 AUG 2020 13:25
PC Close Date & Time	10 AUG 2020 11:59

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.9 °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	10 AUG 2020 19:38
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:44:53

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**	97.2 °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	11 AUG 2020 14:34
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

TIMEPOINT	DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.6 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	12 AUG 2020 14:32
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

| Was **TEMPERATURE** taken? | Yes ● |
| | No ○ |

Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	13 AUG 2020 13:50
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.1 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	14 AUG 2020 12:33
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT   DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ◯
	No ◯
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ◯

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

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	09 AUG 2020 10:21
PC Open Date & Time	09 AUG 2020 10:00
PC Close Date & Time	09 AUG 2020 12:30

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

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	09 AUG 2020 13:27
PC Open Date & Time	09 AUG 2020 13:25
PC Close Date & Time	10 AUG 2020 11:59

TIMEPOINT	DAY 2

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	10 AUG 2020 19:38
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	11 AUG 2020 14:34
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 4
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	12 AUG 2020 14:32
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 5

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	13 AUG 2020 13:50
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 6

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	14 AUG 2020 12:34
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 7

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None ◯
- Does not interfere with activity ◯
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
- Any use of prescription pain reliever or prevents daily activity ◯

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

- Yes ◯
- No ◯

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

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

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

- Yes ◯
- No ◯

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

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

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

- None ◯
- Does not interfere with activity ◯
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
- Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	_____
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

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 ◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	09 AUG 2020 10:23
PC Open Date & Time	09 AUG 2020 10:00
PC Close Date & Time	09 AUG 2020 12:30

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

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 ○

FDA-CBER-2022-1614-0441828

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ● |
| | Yes ○ |

PC Time stamp	09 AUG 2020 13:28
PC Open Date & Time	09 AUG 2020 13:25
PC Close Date & Time	10 AUG 2020 11:59

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 ●

FDA-CBER-2022-1614-0441830

	Yes ◯
PC Time stamp	10 AUG 2020 19:39
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

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

FDA-CBER-2022-1614-0441832

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53

	Yes ◯
PC Time stamp	11 AUG 2020 14:36
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53

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 ●

	Yes ◯
PC Time stamp	12 AUG 2020 14:33
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53

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 ●

	Yes ◯
PC Time stamp	13 AUG 2020 13:50
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

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 ●

	Yes ⬭
PC Time stamp	14 AUG 2020 12:34
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53

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 ◯

	Yes ◯
PC Time stamp	
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3202085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3202085

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

                                                                                      No ○

Continuing Flag   1

US3202085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

| Was Contact Attempted? | Yes ● |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 23 AUG 2020 |

| Please select one status for the follow-up contact | Contact Made ◯ |
| | Contact Not Made ● |

| Comments | ATTEMPTS X3 |

If Contact Not Made, please provide Comments

US3202085

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ⬤

                                                                                     No ◯

Continuing Flag   1

US3202085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 AUG 2020
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	ATTEMPTS X3

If Contact Not Made, please provide Comments

US3202085

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3202085
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 01:55:28**
Generated On: 09 Jun 2021 15:44:53

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | VISIT2 |

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **13 Feb 2021 01:55:28**

Generated On: 09 Jun 2021 15:44:53

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	14:15 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:15
Temperature *(xxx.x)*	37.1 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	82 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4)   **13 Feb 2021 01:55:28**

Generated On: 09 Jun 2021 15:44:53

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	15:29 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 15:29
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 mmHg
Diastolic Blood Pressure units	MMHG

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.

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)*	18 SEP 2020
What was the treatment time? *(00:00-23:59)*	14:32 (24 HR)
Treatment Date and Time (derived)	18 SEP 2020 14:32
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

US3202085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?	Yes ⬤
	No ◯

Collection date *(dd MMM yyyy)*	18 SEP 2020
Collection time *(00:00-23:59)*	14:24 (24 HR)
Collection date and time (derived)	18 SEP 2020 14:24

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Collection date *(dd MMM yyyy)* 18 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:22	18 SEP 2020 14:22
Nasopharyngeal Swab 2	No		

US3202085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

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**	98.4 °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	18 SEP 2020 15:31
PC Open Date & Time	18 SEP 2020 14:52
PC Close Date & Time	18 SEP 2020 17:22

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.5 °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	18 SEP 2020 19:22
PC Open Date & Time	18 SEP 2020 18:17
PC Close Date & Time	19 SEP 2020 11:59

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.2 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	19 SEP 2020 12:01
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

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	20 SEP 2020 12:06
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.1 °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	21 SEP 2020 12:51
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.2 °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	23 SEP 2020 00:12
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.3 °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	23 SEP 2020 13:02
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.0 °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	24 SEP 2020 12:53
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

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	18 SEP 2020 15:31
PC Open Date & Time	18 SEP 2020 14:52
PC Close Date & Time	18 SEP 2020 17:22

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

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	18 SEP 2020 18:59
PC Open Date & Time	18 SEP 2020 18:17
PC Close Date & Time	19 SEP 2020 11:59

TIMEPOINT	DAY 2

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	19 SEP 2020 12:01
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 3
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	20 SEP 2020 12:05
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 4
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	21 SEP 2020 12:51
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 5

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	23 SEP 2020 00:12
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 6

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	23 SEP 2020 13:02
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 7
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	24 SEP 2020 12:53
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

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 ○

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○

PC Time stamp	18 SEP 2020 15:32
PC Open Date & Time	18 SEP 2020 14:52
PC Close Date & Time	18 SEP 2020 17:22

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

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 ⭕

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	18 SEP 2020 18:58
PC Open Date & Time	18 SEP 2020 18:17
PC Close Date & Time	19 SEP 2020 11:59

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 2

HEADACHE

- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING

- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS

- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

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	Yes ◯
PC Time stamp	19 SEP 2020 12:01
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

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 ●

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53

	Yes ◯
PC Time stamp	20 SEP 2020 12:05
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

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 ●

	Yes ◯
PC Time stamp	21 SEP 2020 12:50
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53

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 ●

	Yes ◯
PC Time stamp	23 SEP 2020 00:12
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53

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 ●

	Yes ○
PC Time stamp	23 SEP 2020 13:02
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

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 ●

FDA-CBER-2022-1614-0441886

	Yes ◯
PC Time stamp	24 SEP 2020 12:53
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3202085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3202085

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ○

Continuing Flag   1

US3202085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	1 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 01:55:27**
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

                                                                     No ○

Continuing Flag   1

US3202085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

| 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

US3202085

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 01:55:27**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ⬤

                                                                                     No ◯

Continuing Flag   1

US3202085
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 01:55:28**
Generated On: 09 Jun 2021 15:44:53

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT3

US3202085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **13 Feb 2021 01:55:28**

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	30 OCT 2020
Time of assessment *(00:00-23:59)*	10:34 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 10:34
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	104 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 01:55:28**
Generated On: 09 Jun 2021 15:44:53

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.

US3202085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **13 Feb 2021 01:55:28**

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	30 OCT 2020
Collection time *(00:00-23:59)*	10:51 (24 HR)
Collection date and time (derived)	30 OCT 2020 10:51

US3202085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 01:55:28**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	09 OCT 2020 00:09:29
Patient Cloud Open Date & Time	09 OCT 2020 00:01
Patient Cloud Close Date & Time	13 OCT 2020 23:59

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2020 00:01
Patient Cloud Close Date & Time	20 OCT 2020 23:59

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 02:41:36
Patient Cloud Open Date & Time	23 OCT 2020 00:01
Patient Cloud Close Date & Time	27 OCT 2020 23:59

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 NOV 2020 00:01:52
Patient Cloud Open Date & Time	06 NOV 2020 00:01
Patient Cloud Close Date & Time	10 NOV 2020 23:59

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 NOV 2020 00:06:15
Patient Cloud Open Date & Time	13 NOV 2020 00:01
Patient Cloud Close Date & Time	17 NOV 2020 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	19 NOV 2020 19:19:03
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

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	24 NOV 2020 00:02:10
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	01 DEC 2020 00:01:38
Patient Cloud Open Date & Time	01 DEC 2020 00:01
Patient Cloud Close Date & Time	05 DEC 2020 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 13:21:03
Patient Cloud Open Date & Time	08 DEC 2020 00:01
Patient Cloud Close Date & Time	12 DEC 2020 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	15 DEC 2020 19:04:15
Patient Cloud Open Date & Time	15 DEC 2020 00:01
Patient Cloud Close Date & Time	19 DEC 2020 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	22 DEC 2020 01:27:06
Patient Cloud Open Date & Time	22 DEC 2020 00:01
Patient Cloud Close Date & Time	26 DEC 2020 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	29 DEC 2020 00:01:55
Patient Cloud Open Date & Time	29 DEC 2020 00:01
Patient Cloud Close Date & Time	02 JAN 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 JAN 2021 00:01
Patient Cloud Close Date & Time	16 JAN 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

FDA-CBER-2022-1614-0441916

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 JAN 2021 00:01
Patient Cloud Close Date & Time	23 JAN 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT <div align="right">DAY 173</div>

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2021 00:01
Patient Cloud Close Date & Time	30 JAN 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT   DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0441922

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 FEB 2021 00:01
Patient Cloud Close Date & Time	13 FEB 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Have you been exposed to someone with known SARS-CoV-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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 FEB 2021 00:01
Patient Cloud Close Date & Time	20 FEB 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ⚪

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	23 FEB 2021 00:01
Patient Cloud Close Date & Time	27 FEB 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	05 MAR 2021 09:11:26
Patient Cloud Open Date & Time	02 MAR 2021 00:01
Patient Cloud Close Date & Time	06 MAR 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	09 MAR 2021 01:38:49
Patient Cloud Open Date & Time	09 MAR 2021 00:01
Patient Cloud Close Date & Time	13 MAR 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 MAR 2021 00:01:49
Patient Cloud Open Date & Time	16 MAR 2021 00:01
Patient Cloud Close Date & Time	20 MAR 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 00:05:28
Patient Cloud Open Date & Time	23 MAR 2021 00:01
Patient Cloud Close Date & Time	27 MAR 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	30 MAR 2021 23:51:38
Patient Cloud Open Date & Time	30 MAR 2021 00:01
Patient Cloud Close Date & Time	03 APR 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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	07 APR 2021 12:07:54
Patient Cloud Open Date & Time	06 APR 2021 00:01
Patient Cloud Close Date & Time	10 APR 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 APR 2021 23:30:30
Patient Cloud Open Date & Time	13 APR 2021 00:01
Patient Cloud Close Date & Time	17 APR 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 APR 2021 10:15:57
Patient Cloud Open Date & Time	20 APR 2021 00:01
Patient Cloud Close Date & Time	24 APR 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 APR 2021 00:08:55
Patient Cloud Open Date & Time	27 APR 2021 00:01
Patient Cloud Close Date & Time	01 MAY 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAY 2021 00:01:37
Patient Cloud Open Date & Time	04 MAY 2021 00:01
Patient Cloud Close Date & Time	08 MAY 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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 ⬭

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 MAY 2021 00:01
Patient Cloud Close Date & Time	15 MAY 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 MAY 2021 00:01
Patient Cloud Close Date & Time	22 MAY 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
Fever (Temperature ≥ 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 ⭕

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	29 MAY 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

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

Fever (Temperature $\geq$ 100.4°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 ⭘

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 JUN 2021 00:01
Patient Cloud Close Date & Time	05 JUN 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	12 JUN 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

FDA-CBER-2022-1614-0441950

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2021 00:01
Patient Cloud Close Date & Time	26 JUN 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 JUN 2021 00:01
Patient Cloud Close Date & Time	03 JUL 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-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 ○

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 JUL 2021 00:01
Patient Cloud Close Date & Time	10 JUL 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2021 00:01
Patient Cloud Close Date & Time	17 JUL 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0441958

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 JUL 2021 00:01
Patient Cloud Close Date & Time	24 JUL 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-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 ⬭

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2021 00:01
Patient Cloud Close Date & Time	31 JUL 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ◯

FDA-CBER-2022-1614-0441962

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 AUG 2021 00:01
Patient Cloud Close Date & Time	07 AUG 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	**DAY 369**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	10 AUG 2021 00:01
Patient Cloud Close Date & Time	14 AUG 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	17 AUG 2021 00:01
Patient Cloud Close Date & Time	21 AUG 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ○

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Date and time of submission	
Patient Cloud Open Date & Time	24 AUG 2021 00:01
Patient Cloud Close Date & Time	28 AUG 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT   DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Fever (Temperature ≥ 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 ⬭

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	04 SEP 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	07 SEP 2021 00:01
Patient Cloud Close Date & Time	11 SEP 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

FDA-CBER-2022-1614-0441974

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	14 SEP 2021 00:01
Patient Cloud Close Date & Time	18 SEP 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	25 SEP 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 SEP 2021 00:01
Patient Cloud Close Date & Time	02 OCT 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ⬭

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2021 00:01
Patient Cloud Close Date & Time	09 OCT 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
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 ⭕

FDA-CBER-2022-1614-0441982

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2021 00:01
Patient Cloud Close Date & Time	16 OCT 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2021 00:01
Patient Cloud Close Date & Time	23 OCT 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT   DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	30 OCT 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 NOV 2021 00:01
Patient Cloud Close Date & Time	06 NOV 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 NOV 2021 00:01
Patient Cloud Close Date & Time	13 NOV 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
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 ◯

FDA-CBER-2022-1614-0441992

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 NOV 2021 00:01
Patient Cloud Close Date & Time	20 NOV 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	23 NOV 2021 00:01
Patient Cloud Close Date & Time	27 NOV 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
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 ◯

FDA-CBER-2022-1614-0441996

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 NOV 2021 00:01
Patient Cloud Close Date & Time	04 DEC 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	**DAY 488**

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

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

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

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

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

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

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

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

FDA-CBER-2022-1614-0441998

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	07 DEC 2021 00:01
Patient Cloud Close Date & Time	11 DEC 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ⬭

FDA-CBER-2022-1614-0442000

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	14 DEC 2021 00:01
Patient Cloud Close Date & Time	18 DEC 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-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 ○

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	25 DEC 2021 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	01 JAN 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	08 JAN 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 JAN 2022 00:01
Patient Cloud Close Date & Time	15 JAN 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 JAN 2022 00:01
Patient Cloud Close Date & Time	22 JAN 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ⭘

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	29 JAN 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 FEB 2022 00:01
Patient Cloud Close Date & Time	05 FEB 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
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 ⭕

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	12 FEB 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ◯

FDA-CBER-2022-1614-0442018

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	19 FEB 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ⃝

FDA-CBER-2022-1614-0442020

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 FEB 2022 00:01
Patient Cloud Close Date & Time	26 FEB 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

FDA-CBER-2022-1614-0442022

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	01 MAR 2022 00:01
Patient Cloud Close Date & Time	05 MAR 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ◯ |

FDA-CBER-2022-1614-0442024

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	12 MAR 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
Fever (Temperature ≥ 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 ○

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	19 MAR 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
Fever (Temperature ≥ 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 ⚪

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 MAR 2022 00:01
Patient Cloud Close Date & Time	26 MAR 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-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 ⬭

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	29 MAR 2022 00:01
Patient Cloud Close Date & Time	02 APR 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Symptom	
Fever (Temperature ≥ 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 ⬭

FDA-CBER-2022-1614-0442032

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 APR 2022 00:01
Patient Cloud Close Date & Time	09 APR 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
Fever (Temperature ≥ 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 ⭘

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 APR 2022 00:01
Patient Cloud Close Date & Time	16 APR 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	**DAY 621**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Symptom	
Fever (Temperature ≥ 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 ⬭

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 APR 2022 00:01
Patient Cloud Close Date & Time	23 APR 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ◯

FDA-CBER-2022-1614-0442038

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 MAY 2022 00:01
Patient Cloud Close Date & Time	07 MAY 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT   DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	10 MAY 2022 00:01
Patient Cloud Close Date & Time	14 MAY 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT   DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

FDA-CBER-2022-1614-0442044

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	17 MAY 2022 00:01
Patient Cloud Close Date & Time	21 MAY 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	28 MAY 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ⬭

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	04 JUN 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT   DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	07 JUN 2022 00:01
Patient Cloud Close Date & Time	11 JUN 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	14 JUN 2022 00:01
Patient Cloud Close Date & Time	18 JUN 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	25 JUN 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT   DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature $\geq$ 100.4°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 ⃝

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	02 JUL 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	05 JUL 2022 00:01
Patient Cloud Close Date & Time	09 JUL 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ○

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 JUL 2022 00:01
Patient Cloud Close Date & Time	16 JUL 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this ◯ message and will call the study clinic immediately
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 JUL 2022 00:01
Patient Cloud Close Date & Time	23 JUL 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ⭕

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 AUG 2022 00:01
Patient Cloud Close Date & Time	06 AUG 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

FDA-CBER-2022-1614-0442068

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 AUG 2022 00:01
Patient Cloud Close Date & Time	13 AUG 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 AUG 2022 00:01
Patient Cloud Close Date & Time	20 AUG 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	23 AUG 2022 00:01
Patient Cloud Close Date & Time	27 AUG 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 AUG 2022 00:01
Patient Cloud Close Date & Time	03 SEP 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ⬭

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 SEP 2022 00:01
Patient Cloud Close Date & Time	10 SEP 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ◯

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 SEP 2022 00:01
Patient Cloud Close Date & Time	17 SEP 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Date and time of submission	
Patient Cloud Open Date & Time	20 SEP 2022 00:01
Patient Cloud Close Date & Time	24 SEP 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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°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 ⭕

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ≥ 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 ◯

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	08 OCT 2022 23:59

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-0442086

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 OCT 2022 00:01
Patient Cloud Close Date & Time	15 OCT 2022 23:59

US3202085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:44:53

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
Yes	Yes	05 MAR 2021 09:11:58

US3202085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **26 Mar 2021 12:39:30**

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3202085

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **26 Mar 2021 12:39:30**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3202085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **09 Apr 2021 13:51:46**

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 DEC 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3202085

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 13:51:46**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3202085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **09 Apr 2021 13:52:05**

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 JAN 2021
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	LEFT A VOICE MESSAGE

If Contact Not Made, please provide Comments

US3202085

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 13:52:05**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3202085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **09 Apr 2021 13:52:05**

Generated On: 09 Jun 2021 15:44:53

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

US3202085
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **09 Apr 2021 13:52:05**
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3202085
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53

Was this visit performed?	Yes	◯
	No	◯

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3202085
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

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)	_____

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.

US3202085
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:44:53

Was the sample collected?	Yes ◯
	No ◯

Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

US3202085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3202085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 APR 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3202085

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: [(b) (4)] **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ⬤

                                                             No ◯

Continuing Flag   1

US3202085
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

| 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 _____

Is the participant continuing to the next visit?   Yes ◯

No ◯

Continuing Flag

US3202085
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:44:53

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	

Type of Contact	
	Clinic Visit - Scheduled ◯
	Clinical Visit - Unscheduled ◯
	Safety Call ◯
	Convalescent Tele-visit ◯

Has the subject reported symptoms of SARS-COV-2?	Yes ◯
	No ◯

Generate Next COVID-19 Assessment	Yes $\bigcirc$
	No $\bigcirc$

US3202085

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

Form: Visit Date

Data signed: (b) (4) **09 Apr 2021 15:21:19**

Generated On: 09 Jun 2021 15:44:53

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	UNBLND_DECIDE

US3202085

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

Form: Unblinding

Data signed: (b) (4) **28 Apr 2021 07:01:29**

Generated On: 09 Jun 2021 15:44:53

Date of updated informed consent *(dd MMM yyyy)*	08 MAR 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)*	08 MAR 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	1
Continuing with mRNA-1273	1

US3202085

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **09 Apr 2021 13:51:45**

Generated On: 09 Jun 2021 15:44:53

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

US3202085

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **09 Apr 2021 13:51:45**

Generated On: 09 Jun 2021 15:44:53

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	11 MAR 2021
Time of assessment *(00:00-23:59)*	15:15 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 15:15
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	98 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	96 mmHg
Diastolic Blood Pressure units	MMHG

US3202085

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **09 Apr 2021 13:51:45**

Generated On: 09 Jun 2021 15:44:53

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	16:27 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 16:27
Temperature (xxx.x)	37.0 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3202085

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:51:45

Generated On: 09 Jun 2021 15:44:53

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.

Was study treatment given?	Yes ⬤
	No ◯

If No, reason not given	Participant declined due to Adverse Event ◯
	Physician withheld dose due to Adverse Event ◯
	Death ◯
	Lost To Follow-Up ◯
	Physician Decision ◯
	Pregnancy ◯
	Protocol Deviation ◯
	Study Terminated by Sponsor ◯
	Withdrawal of Consent by Participant ◯
	Confirmed COVID-19 ◯
	Other ◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	11 MAR 2021
What was the treatment time? *(00:00-23:59)*	15:55 (24 HR)
Treatment Date and Time (derived)	11 MAR 2021 15:55
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

Was the sample collected?   Yes ◯

                                                             No ⬤

Collection date *(dd MMM yyyy)*

Collection time *(00:00-23:59)*

Collection date and time (derived)

US3202085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **09 Apr 2021 13:51:45**

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?   Yes ◯

                                                                         No ⬤

Collection date *(dd MMM yyyy)*

Collection time *(00:00 - 23:59)*

Collection Date and Time (derived)

US3202085

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

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 13:51:45**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　1

US3202085
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **09 Apr 2021 13:52:05**
Generated On: 09 Jun 2021 15:44:53

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 19 MAR 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3202085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **09 Apr 2021 13:52:05**

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag	1
OLD29 Placebo Flag	1

US3202085
Folder: OL-D29 (1)
Form: Visit Date
Data signed: ▨ (b) (4) ▨ **12 Apr 2021 18:08:40**
Generated On: 09 Jun 2021 15:44:53

Was this visit performed?	Yes ⬤
	No ⬭

Visit date (dd MMM yyyy)	9 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ⬭
	Clinic ⬤

Folder OID	OLD29

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)   **12 Apr 2021 18:08:40**

Generated On: 09 Jun 2021 15:44:53

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	9 APR 2021
Time of assessment *(00:00-23:59)*	13:11 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 13:11
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **12 Apr 2021 18:08:40**

Generated On: 09 Jun 2021 15:44:53

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	9 APR 2021
Time of assessment *(00:00-23:59)*	14:30 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 14:30
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	82 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	98 mmHg
Diastolic Blood Pressure units	MMHG

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.

| Was study treatment given? | Yes ● |
| | No ○ |

If No, reason not given	Participant declined due to Adverse Event ○
	Physician withheld dose due to Adverse Event ○
	Death ○
	Lost To Follow-Up ○
	Physician Decision ○
	Pregnancy ○
	Protocol Deviation ○
	Study Terminated by Sponsor ○
	Withdrawal of Consent by Participant ○
	Confirmed COVID-19 ○
	Other ○

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	9 APR 2021
What was the treatment time? *(00:00-23:59)*	13:54 (24 HR)
Treatment Date and Time (derived)	9 APR 2021 13:54
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

US3202085
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **12 Apr 2021 18:08:40**
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3202085
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

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 _____

Is the participant continuing to the next visit?   Yes ◯

                                                                    No ◯

Continuing Flag

US3202085

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **19 Mar 2021 13:04:06**

Generated On: 09 Jun 2021 15:44:53

Did the participant experience any adverse events?   Yes ●

                                                                                                                       No ○

If Yes, enter details on the Adverse Events form.

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: ▒ (b) (4) ▒ 22 Apr 2021 17:54:04
Generated On: 09 Jun 2021 15:44:53

AEID	
Adverse event	POST TRAUMATIC STRESS DISORDER

Was this a medically-attended AE?	Yes ◯
	No ⬤

Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤

Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤

Start date *(dd MMM yyyy)*	15 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?	Yes ⬤
	No ◯

If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯

Is the adverse event serious?	Yes ◯
	No ⬤

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	
	None ●
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ○

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	
	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ○
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ●

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT TO LET US KNOW NEW RX NAME- UNABLE TO RECALL AT VS TODAY
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

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AEID	USA-US128-2021-MRNA-1273-P30 1000010
Adverse event	PANCREATITIS

Was this a medically-attended AE? Yes ● No ○

Was this a Solicited Adverse Reaction? Yes ○ No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ○ No ●

Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	09 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity Grade 1/Mild ○ Grade 2/Moderate ○ Grade 3/Severe ● Grade 4 ○

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	15 JAN 2021
Hospital Discharge Date *(dd MMM yyyy)*	09 FEB 2021

Admitted to ICU? Yes ● No ○ Unknown ○

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Folder: Adverse Events

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Number of Days in ICU	13
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- ● Not Related
- ○ Related
- ○ Not Applicable

Relationship to Study Procedure

- ● Not Related
- ○ Related
- ○ Not Applicable

Action taken with investigational product

- ○ None
- ○ Dose Delayed
- ○ Investigational Product Withdrawn
- ● Not Applicable

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

Outcome

- ○ Fatal
- ○ Not Recovered/Not Resolved
- ● Recovered/Resolved
- ○ Recovered/Resolved with Sequelae
- ○ Recovering/Resolving
- ○ Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

	RECORDS REQUESTED FROM HOSPITALIZATION. SITE MADE AWARE OF THIS SAE ON 22FEB2021. MEDICAL RECORDS HAVE BEEN RECEIVED AND DISCHARGE SUMMARY PROVIDED TO SAFETY REPORTING TEAM. SUBJECT ADMITTED FOR PANCREATITIS, BUT DEVELOPED NUMEROUS OTHER CONDITIONS (ALSO ADDED AS AES AND SAES) AS LEARNED WHEN RECORDS WERE RECEIVED.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

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AEID	USA-US128-2021-MRNA-1273-P30 1000010
Adverse event	DIABETIC KETOACIDOSIS

Was this a medically-attended AE? Yes ● No ○

Was this a Solicited Adverse Reaction? Yes ○ No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ○ No ●

Start date *(dd MMM yyyy)* 15 JAN 2021

Start time *(00:00-23:59)*

AE start date and time (derived)

Ongoing? Yes ○ No ●

   If not Ongoing, end date *(dd MMM yyyy)* 09 FEB 2021

   End time *(00:00-23:59)*

AE End Date and Time (derived)

Severity Grade 1/Mild ○ Grade 2/Moderate ○ Grade 3/Severe ● Grade 4 ○

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	15 JAN 2021
Hospital Discharge Date *(dd MMM yyyy)*	09 FEB 2021

   Admitted to ICU? Yes ● No ○ Unknown ○

Number of Days in ICU	13
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related	⬤
	Related	◯
	Not Applicable	◯

Relationship to Study Procedure	Not Related	⬤
	Related	◯
	Not Applicable	◯

Action taken with investigational product	None	◯
	Dose Delayed	◯
	Investigational Product Withdrawn	◯
	Not Applicable	⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal	◯
	Not Recovered/Not Resolved	◯
	Recovered/Resolved	⬤
	Recovered/Resolved with Sequelae	◯
	Recovering/Resolving	◯
	Unknown	◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

	RECORDS RECEIVED TODAY FROM HOSPITALIZATION AS REQUESTED WHEN SUBJECT REPORTED PANCREATITIS. THE RECORDS REVEALED ADDITIONAL DIAGNOSES RELATED TO THE HOSPITALIZATION
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

AEID	USA-US128-2021-MRNA-1273-P30 1000010
Adverse event	SEPSIS

Was this a medically-attended AE?   Yes ⬤   No ◯

Was this a Solicited Adverse Reaction?   Yes ◯   No ⬤

Is this event a confirmed diagnosis of Symptomatic Covid-19?   Yes ◯   No ⬤

Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ◯   No ⬤

If not Ongoing, end date *(dd MMM yyyy)*	09 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity   Grade 1/Mild ◯   Grade 2/Moderate ◯   Grade 3/Severe ⬤   Grade 4 ◯

Is the adverse event serious?   Yes ⬤   No ◯

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	15 JAN 2021
Hospital Discharge Date *(dd MMM yyyy)*	09 FEB 2021

Admitted to ICU?   Yes ⬤   No ◯   Unknown ◯

Number of Days in ICU	13
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product
- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure
- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product
- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome
- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative	OCCURRED WITH THE PANCREATITIS AND DKA SAES AS LEARNED PER HOSPITAL RECORDS RECEIVED
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

AEID	USA-US128-2021-MRNA-1273-P30 1000010
Adverse event	ACUTE HYPOXIC RESPIRATORY FAILURE

Was this a medically-attended AE?　　Yes ●　No ○

Was this a Solicited Adverse Reaction?　　Yes ○　No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?　　Yes ○　No ●

Start date *(dd MMM yyyy)*　　15 JAN 2021

Start time *(00:00-23:59)*

AE start date and time (derived)

Ongoing?　　Yes ○　No ●

If not Ongoing, end date *(dd MMM yyyy)*　　30 JAN 2021

End time *(00:00-23:59)*

AE End Date and Time (derived)

Severity　　Grade 1/Mild ○　Grade 2/Moderate ○　Grade 3/Severe ●　Grade 4 ○

Is the adverse event serious?　　Yes ●　No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	15 JAN 2021
Hospital Discharge Date *(dd MMM yyyy)*	9 FEB 2021
Admitted to ICU?	Yes ●　No ○　Unknown ○

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Number of Days in ICU	13
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
Not Related	⬤
Related	◯
Not Applicable	◯

Relationship to Study Procedure	
Not Related	⬤
Related	◯
Not Applicable	◯

Action taken with investigational product	
None	◯
Dose Delayed	◯
Investigational Product Withdrawn	◯
Not Applicable	⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

Outcome	
Fatal	◯
Not Recovered/Not Resolved	◯
Recovered/Resolved	⬤
Recovered/Resolved with Sequelae	◯
Recovering/Resolving	◯
Unknown	◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

	OCCURRED DURING HOSPITALIZATION FOR PANCREATITIS, SEPSIS, ETC. MICROBIOLOGY TESTS ALL NEGATIVE. FINAL NOTE FROM INFECTIOUS DISEASE SPECIALIST CONSULTATIONS STATE, "FEVER/WBC POSSIBLY ALL SEC TO RESOLVING SEVERE PANCREATITIS" AND RESULTS NOTE THAT F/U BCX, SARS-COV-2, C-DIFF WERE NEGATIVE. SPUTUM AND ASCITES MICROBIOLOGY LAB NOTES STATE "NO GROWTH TO DATE" FOR CULTURES
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

AEID	USA-US128-2021-MRNA-1273-P30 1000010
Adverse event	ACUTE RENAL FAILURE UNSPECIFIED

Was this a medically-attended AE? Yes ● No ○

Was this a Solicited Adverse Reaction? Yes ○ No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ○ No ●

Start date *(dd MMM yyyy)* 15 JAN 2021

Start time *(00:00-23:59)*

AE start date and time (derived)

Ongoing? Yes ○ No ●

   If not Ongoing, end date *(dd MMM yyyy)* 26 JAN 2021

   End time *(00:00-23:59)*

AE End Date and Time (derived)

Severity Grade 1/Mild ○ Grade 2/Moderate ○ Grade 3/Severe ● Grade 4 ○

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	15 JAN 2021
Hospital Discharge Date *(dd MMM yyyy)*	09 FEB 2021

  Admitted to ICU? Yes ● No ○ Unknown ○

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

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Number of Days in ICU	13
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
Not Related	●
Related	○
Not Applicable	○

Relationship to Study Procedure	
Not Related	●
Related	○
Not Applicable	○

Action taken with investigational product	
None	○
Dose Delayed	○
Investigational Product Withdrawn	○
Not Applicable	●

Other action taken (check all that apply)

None	False
Concomitant Medication	False
Concomitant Procedure	True

Outcome	
Fatal	○
Not Recovered/Not Resolved	○
Recovered/Resolved	●
Recovered/Resolved with Sequelae	○
Recovering/Resolving	○
Unknown	○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	TEMPORARY DIALYSIS DURING HOSPITALIZATION
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

AEID	
Adverse event	TYPE 2 DIABETES MELLITUS

Was this a medically-attended AE? Yes ⬤ No ◯

Was this a Solicited Adverse Reaction? Yes ◯ No ⬤

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ◯ No ⬤

Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ⬤ No ◯

If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity Grade 1/Mild ◯ Grade 2/Moderate ⬤ Grade 3/Severe ◯ Grade 4 ◯

Is the adverse event serious? Yes ◯ No ⬤

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU? Yes ◯ No ◯ Unknown ◯

Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	
	None ○
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	
	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ○
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ●
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 17:54:04

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AEID	
Adverse event	ADYNAMIC ILEUS
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	09 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ○
	Grade 3/Severe ●
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Folder: Adverse Events

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Data signed: (b) (4) **22 Apr 2021 17:54:04**

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	
	Not Related ⬤
	Related ◯
	Not Applicable ◯

Action taken with investigational product	
	None ◯
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ⬤

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	
	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

AEID	
Adverse event	CONSTIPATION
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	29 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
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 ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	
	None ○
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	
	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4)　22 Apr 2021 17:54:04

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AEID	
Adverse event	GASTRIC ULCER WITHOUT HEMORRHAGE OR PERFORATION

Was this a medically-attended AE?　　Yes ⬤　No ◯

Was this a Solicited Adverse Reaction?　　Yes ◯　No ⬤

Is this event a confirmed diagnosis of Symptomatic Covid-19?　　Yes ◯　No ⬤

Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　　Yes ⬤　No ◯

If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity　　Grade 1/Mild ⬤　Grade 2/Moderate ◯　Grade 3/Severe ◯　Grade 4 ◯

Is the adverse event serious?　　Yes ◯　No ⬤

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?　　Yes ◯　No ◯　Unknown ◯

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ◯
- Not Recovered/Not Resolved ⬤
- Recovered/Resolved ◯
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

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AEID	
Adverse event	UNSPECIFIED GASTRITIS WITHOUT BLEEDING
Was this a medically-attended AE?	Yes ⬤
	No ⭘
Was this a Solicited Adverse Reaction?	Yes ⭘
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ⭘
	No ⬤
Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ⭘
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	9 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ⭘
	Grade 3/Severe ⭘
	Grade 4 ⭘
Is the adverse event serious?	Yes ⭘
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ⭘
	No ⭘
	Unknown ⭘

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	
	None ○
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	
	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

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AEID	
Adverse event	ALCOHOL WITHDRAWAL
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	09 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related	⬤
	Related	◯
	Not Applicable	◯
Relationship to Study Procedure	Not Related	⬤
	Related	◯
	Not Applicable	◯
Action taken with investigational product	None	◯
	Dose Delayed	◯
	Investigational Product Withdrawn	◯
	Not Applicable	⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal	◯
	Not Recovered/Not Resolved	◯
	Recovered/Resolved	⬤
	Recovered/Resolved with Sequelae	◯
	Recovering/Resolving	◯
	Unknown	◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

AEID	
Adverse event	SUICIDAL IDEATIONS
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	22 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
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 ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure
- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product
- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ⬤

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome
- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

AEID	USA-US128-2021-MRNA-1273-P30 1000010
Adverse event	PNEUMONIA

Was this a medically-attended AE? Yes ● No ○

Was this a Solicited Adverse Reaction? Yes ○ No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ○ No ●

Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	05 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity Grade 1/Mild ○ Grade 2/Moderate ○ Grade 3/Severe ● Grade 4 ○

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	15 JAN 2021
Hospital Discharge Date *(dd MMM yyyy)*	09 FEB 2021

Admitted to ICU? Yes ● No ○ Unknown ○

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

Number of Days in ICU	13
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
Not Related	●
Related	◯
Not Applicable	◯

Relationship to Study Procedure	
Not Related	●
Related	◯
Not Applicable	◯

Action taken with investigational product	
None	◯
Dose Delayed	◯
Investigational Product Withdrawn	◯
Not Applicable	●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	
Fatal	◯
Not Recovered/Not Resolved	◯
Recovered/Resolved	●
Recovered/Resolved with Sequelae	◯
Recovering/Resolving	◯
Unknown	◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT ADMITTED FOR PANCREATITIS AND FOUND TO HAVE PNEUMONIA-SAME HOSPITALIZATION AS OTHER SAES
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003 EAB) (1725)

Admitted to ICU Derived (CSA Programming Field Only)   1

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Data signed: [(b) (4)] **22 Apr 2021 17:54:04**
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AEID	
Adverse event	LOCULATED ASCITES
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	27 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	04 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ○
	Grade 2/Moderate ●
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	
	None ○
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	False
Concomitant Procedure	True

Outcome	
	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	
	None ○
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	
	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ○
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ●
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

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AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	27 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related	●
	Related	○
	Not Applicable	○

Relationship to Study Procedure	Not Related	●
	Related	○
	Not Applicable	○

Action taken with investigational product	None	○
	Dose Delayed	○
	Investigational Product Withdrawn	○
	Not Applicable	●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal	○
	Not Recovered/Not Resolved	●
	Recovered/Resolved	○
	Recovered/Resolved with Sequelae	○
	Recovering/Resolving	○
	Unknown	○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

AEID	
Adverse event	DYSPHONIA
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	30 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	27 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ⬤
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ⬤
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ⬤

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Data signed: (b) (4) **22 Apr 2021 17:54:04**
Generated On: 09 Jun 2021 15:44:53

AEID	
Adverse event	HYPERTRIGLYCERIDEMIA
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date (dd MMM yyyy)	15 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	
	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	
	None ○
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	
	Fatal ○
	Not Recovered/Not Resolved ●
	Recovered/Resolved ○
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3202085

Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) **22 Apr 2021 17:54:04**

Generated On: 09 Jun 2021 15:44:53

AEID	
Adverse event	INTERMITTENT ELECTROLYTE IMBALANCES

Was this a medically-attended AE?   Yes ●   No ○

Was this a Solicited Adverse Reaction?   Yes ○   No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?   Yes ○   No ●

Start date *(dd MMM yyyy)*	15 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ○   No ●

If not Ongoing, end date *(dd MMM yyyy)*	09 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity   Grade 1/Mild ○   Grade 2/Moderate ●   Grade 3/Severe ○   Grade 4 ○

Is the adverse event serious?   Yes ○   No ●

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?   Yes ○   No ○   Unknown ○

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ●
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

FDA-CBER-2022-1614-0442172

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **09 Apr 2021 13:51:45**

Generated On: 09 Jun 2021 15:44:53

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

                                                                      No ◯

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	PROPRANOLOL

Prophylaxis

Yes ◯
No ⬤

Indication	MIGRAINE
Dose per administration	20

Dose unit

mg ⬤
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ⬤
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **22 Apr 2021 17:54:05**
Generated On: 09 Jun 2021 15:44:53

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	10 APR 2019
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	TOPIRAMATE

Prophylaxis	Yes ⚪
	No ⚫

Indication	MIGRAINE
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 ⚪

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JUN 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	METHIMAZOLE

Prophylaxis

- Yes ○
- No ⬤

Indication	HYPERTHYROID
Dose per administration	5

Dose unit

- mg ⬤
- ug ○
- mL ○
- g ○
- IU ○
- tablet ○
- capsule ○
- puff ○
- Other ○

If dose unit is Other, specify _____

Frequency

- once daily ⬤
- twice daily ○
- three times daily ○
- four times daily ○
- every other day ○
- every week ○
- every month ○
- as needed ○
- once ○
- unknown ○
- other ○

If frequency is Other, specify _____

Route of administration

- Oral ⬤
- Topical ○
- Subcutaneous ○
- Transdermal ○
- Intraocular ○

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 JUN 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	REMERON
Prophylaxis	Yes ◯
	No ⬤
Indication	POST TRAUMATIC STRESS DISORDER
Dose per administration	15
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperitoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	ZOSYN

Prophylaxis
- Yes ⭕
- No ⬤

Indication	SEPSIS
Dose per administration	3/0.375

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 ⭕

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	02 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	BACTROBAN NASAL

Prophylaxis	Yes ⬤
	No ◯

Indication	PROPHYLAXIS-(IN HOSPITAL WHEN INTUBATED)

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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Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	⬤
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	22 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	PEPCID
Prophylaxis	Yes ⦾
	No ⬤
Indication	GASTRITIS
Dose per administration	20
Dose unit	mg ⬤
	ug ⦾
	mL ⦾
	g ⦾
	IU ⦾
	tablet ⦾
	capsule ⦾
	puff ⦾
	Other ⦾
If dose unit is Other, specify	
Frequency	once daily ⦾
	twice daily ⬤
	three times daily ⦾
	four times daily ⦾
	every other day ⦾
	every week ⦾
	every month ⦾
	as needed ⦾
	once ⦾
	unknown ⦾
	other ⦾
If frequency is Other, specify	
Route of administration	Oral ⦾
	Topical ⦾
	Subcutaneous ⦾
	Transdermal ⦾
	Intraocular ⦾

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	09 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	LACTATED RINGERS

Prophylaxis	Yes ◯
	No ⬤

Indication	SEPSIS

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 ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*   17 JAN 2021

Start date completely unknown   False

Ongoing?   Yes ◯   No ⬤

If not Ongoing, End date *(dd MMM yyyy)*   17 JAN 2021

Was this medication taken for solicited event?   Yes ◯   No ⬤

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived)   802 ◯   803 ◯   804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	SODIUM CHLORIDE 0.9%

Prophylaxis

Yes ◯
No ⬤

Indication	INTERMITTENT ELECTROLYTE IMBALANCES
Dose per administration	100

Dose unit

mg ◯
ug ◯
mL ⬤
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ◯
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ⬤
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ◯
Topical ◯
Subcutaneous ◯
Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	⬤
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

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Name of Medication	ZOSYN

Prophylaxis

Yes ◯

No ⬤

Indication	SEPSIS
Dose per administration	4/0.5

Dose unit

mg ◯

ug ◯

mL ◯

g ⬤

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify _____

Frequency

once daily ⬤

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ◯

unknown ◯

other ◯

If frequency is Other, specify _____

Route of administration

Oral ◯

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	17 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	ALBUMIN HUMAN 5%

Prophylaxis	Yes ◯
	No ⬤

Indication	SEPSIS
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 ◯

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	17 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	ALBUTEROL HFA

Prophylaxis — Yes ◯ No ⬤

Indication	1.) DYSPNEA
	2.) PNEUMONIA

Dose per administration	90

Dose unit
- mg ◯
- ug ⬤
- mL ◯
- g ◯
- IU ◯
- tablet ◯
- capsule ◯
- puff ◯
- Other ◯

If dose unit is Other, specify _____

Frequency
- once daily ◯
- twice daily ◯
- three times daily ◯
- four times daily ⬤
- every other day ◯
- every week ◯
- every month ◯
- as needed ◯
- once ◯
- unknown ◯
- other ◯

If frequency is Other, specify _____

Route of administration
- Oral ◯
- Topical ◯
- Subcutaneous ◯
- Transdermal ◯

	Intraocular ◯
	Intramuscular ◯
	Respiratory (Inhalation) ⬤
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	PANTOPRAZOLE

Prophylaxis		
	Yes	⚪
	No	⚫

Indication	GASTRIC ULCER
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	⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **22 Apr 2021 17:54:05**
Generated On: 09 Jun 2021 15:44:53

Intramuscular	○
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	●
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	27 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	8 FEB 2021
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ●

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	LIPTOR

Prophylaxis		
	Yes	◯
	No	⬤

Indication	HYPERTRIGLYCERIDEMIA
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	◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	30 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	TYLENOL
Prophylaxis	Yes ○
	No ⬤
Indication	SEPSIS
Dose per administration	650
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 ○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	17 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	BENADRYL
Prophylaxis	Yes ●
	No ○
Indication	PROPHYLAXIS DURING DIALYSIS
Dose per administration	50
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ●
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○

	Intraocular ◯
	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	17 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	DEXTROSE 5%/SALINE .45%

Prophylaxis	
Yes	◯
No	●

Indication	SEPSIS
Dose per administration	125

Dose unit	
mg	◯
ug	◯
mL	◯
g	◯
IU	◯
tablet	◯
capsule	◯
puff	◯
Other	●

If dose unit is Other, specify	ML/HR

Frequency	
once daily	◯
twice daily	◯
three times daily	◯
four times daily	◯
every other day	◯
every week	◯
every month	◯
as needed	◯
once	◯
unknown	◯
other	●

If frequency is Other, specify	CONTINOUS

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

	Intramuscular ⃝
	Respiratory (Inhalation) ⃝
	Intralesional ⃝
	Intraperiteoneal ⃝
	Nasal ⃝
	Vaginal ⃝
	Rectal ⃝
	Intravenous ⃝
	Intravenous Bolus ⃝
	Intravenous Drip ⬤
	Other ⃝

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⃝
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	18 JAN 2021
Was this medication taken for solicited event?	Yes ⃝
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⃝
	803 ⃝
	804 ⃝

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	MAGNESIUM SULFATE/WATER 2000 MG/50 ML

Prophylaxis

Yes ◯
No ⬤

Indication	INTERMITTENT ELECTROLYTE IMBALANCES
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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Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	⬤
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	17 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	PRECEDEX

Prophylaxis   Yes ◯
                                                     No ⬤

Indication	ACUTE HYPOXIC RESPIRATORY FAILURE
Dose per administration	100

Dose unit   mg ◯
                                                     ug ◯
                                                     mL ⬤
                                                      g ◯
                                                     IU ◯
                                                 tablet ◯
                                                capsule ◯
                                                   puff ◯
                                                  Other ◯

If dose unit is Other, specify _____

Frequency   once daily ◯
                                              twice daily ◯
                                        three times daily ◯
                                         four times daily ◯
                                          every other day ◯
                                               every week ◯
                                              every month ◯
                                                as needed ◯
                                                     once ⬤
                                                  unknown ◯
                                                    other ◯

If frequency is Other, specify _____

Route of administration   Oral ◯
                                                 Topical ◯
                                            Subcutaneous ◯
                                             Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	17 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	LIBRIUM
Prophylaxis	Yes ◯
	No ⬤
Indication	ALCOHOL WITHDRAWAL
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 ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Data signed: (b) (4) **22 Apr 2021 17:54:05**
Generated On: 09 Jun 2021 15:44:53

Intramuscular	○
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	○
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	25 JAN 2021
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ●

Name of Medication	HEPARIN
Prophylaxis	Yes ●
	No ○
Indication	DVT PROPHYLAXIS
Dose per administration	5000
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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Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	18 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	30 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	ACETAMINOPHEN

Prophylaxis	Yes ◯
	No ⬤

Indication	SEPSIS
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 ◯

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ●
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	18 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	18 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4)   **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	HUMULIN R

Prophylaxis	Yes ⚪
	No ⚫

Indication	DIABETES MELLITUS T2

Dose per administration	0.5

Dose unit	mg ⚪
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚫

If dose unit is Other, specify	U/HR

Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚫

If frequency is Other, specify	CONTINUOUS

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

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EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	⬤
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	18 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	DILAUDID
Prophylaxis	Yes ⬭
	No ⬤
Indication	PANCREATITIS
Dose per administration	0.3
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 ⬭
	Intraocular ⬭

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	19 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	FENTANYL CITRATE

Prophylaxis	Yes ◯
	No ⬤

Indication	PANCREATITIS

Dose per administration	50

Dose unit	mg ◯
	ug ⬤
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify	

Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ⬤
	once ◯
	unknown ◯
	other ◯

If frequency is Other, specify	

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

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ⬤
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	POTASSIUM CHLORIDE
Prophylaxis	Yes ⚪
	No ⬤
Indication	INTERMITTENT ELECTROLYTE IMBALANCES
Dose per administration	20
Dose unit	mg ⚪
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⬤
If dose unit is Other, specify	MEQ
Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⬤
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⚪
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪

Intraocular	⭘
Intramuscular	⭘
Respiratory (Inhalation)	⭘
Intralesional	⭘
Intraperiteoneal	⭘
Nasal	⭘
Vaginal	⭘
Rectal	⭘
Intravenous	⬤
Intravenous Bolus	⭘
Intravenous Drip	⭘
Other	⭘

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⭘
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	19 JAN 2021
Was this medication taken for solicited event?	Yes ⭘
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⭘
	803 ⭘
	804 ⬤

Name of Medication	COLACE
Prophylaxis	Yes ◯
	No ⬤
Indication	CONSTIPATION
Dose per administration	100
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ◯
	twice daily ⬤
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

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Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	SENNA-LAX

Prophylaxis	
	Yes ○
	No ●

Indication	CONSTIPATION
Dose per administration	8.6

Dose unit	
	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify _____

Frequency	
	once daily ○
	twice daily ●
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○

If frequency is Other, specify _____

Route of administration	
	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	LABETALOL

Prophylaxis

Yes ◯

No ⬤

Indication	ACUTE RENTAL FAILURE UNSPECIFIED
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	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	MIRALAX
Prophylaxis	Yes ◯
	No ⬤
Indication	CONSTIPATION
Dose per administration	17

Dose unit
- mg ◯
- ug ◯
- mL ◯
- g ⬤
- IU ◯
- tablet ◯
- capsule ◯
- puff ◯
- Other ◯

If dose unit is Other, specify _____

Frequency
- once daily ⬤
- twice daily ◯
- three times daily ◯
- four times daily ◯
- every other day ◯
- every week ◯
- every month ◯
- as needed ◯
- once ◯
- unknown ◯
- other ◯

If frequency is Other, specify _____

Route of administration
- Oral ⬤
- Topical ◯
- Subcutaneous ◯
- Transdermal ◯
- Intraocular ◯

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	21 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	LANTUS
Prophylaxis	Yes ◯
	No ⬤
Indication	DIABETES MELLITUS T2
Dose per administration	20
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	UNITS
Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ◯
	Topical ◯
	Subcutaneous ⬤
	Transdermal ◯
	Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	⬭
Respiratory (Inhalation)	⬭
Intralesional	⬭
Intraperiteoneal	⬭
Nasal	⬭
Vaginal	⬭
Rectal	⬭
Intravenous	⬭
Intravenous Bolus	⬭
Intravenous Drip	⬭
Other	⬭

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	21 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	27 JAN 2021
Was this medication taken for solicited event?	Yes ⬭
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬤

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	BISACODYL

Prophylaxis

Yes ⦸

No ⬤

Indication	CONSTIPATION
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 ◯

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	21 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	21 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	HUMALOG
Prophylaxis	Yes ⚪
	No ⬤
Indication	DM T2
Dose per administration	3
Dose unit	mg ⚪
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⬤
If dose unit is Other, specify	UNITS
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 ⚪

Intramuscular	○
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	○
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	21 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	VALIUM
Prophylaxis	Yes ○
	No ●
Indication	ALCOHOL (ETOH) WITHDRAWAL
Dose per administration	5
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ●
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○

	Intraocular ⬭
	Intramuscular ⬭
	Respiratory (Inhalation) ⬭
	Intralesional ⬭
	Intraperiteoneal ⬭
	Nasal ⬭
	Vaginal ⬭
	Rectal ⬭
	Intravenous ⬤
	Intravenous Bolus ⬭
	Intravenous Drip ⬭
	Other ⬭

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	21 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	21 JAN 2021
Was this medication taken for solicited event?	Yes ⬭
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬭

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	ROXICODONE

Prophylaxis

Yes ⚪

No ⚫

Indication	PANCREATITIS
Dose per administration	5

Dose unit

mg ⚫
ug ⚪
mL ⚪
g ⚪
IU ⚪
tablet ⚪
capsule ⚪
puff ⚪
Other ⚪

If dose unit is Other, specify

Frequency

once daily ⚪
twice daily ⚪
three times daily ⚪
four times daily ⚪
every other day ⚪
every week ⚪
every month ⚪
as needed ⚫
once ⚪
unknown ⚪
other ⚪

If frequency is Other, specify

Route of administration

Oral ⚫
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪
Intraocular ⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	21 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	2 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	CATAPRES
Prophylaxis	Yes ◯
	No ⬤
Indication	ACUTE RENAL FAILURE
Dose per administration	0.2
Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ⬤
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ◯
	Topical ◯
	Subcutaneous ◯
	Transdermal ⬤
	Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	22 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	09 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ⬤
	804 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	LACTATED RINGERS

Prophylaxis

Yes ◯

No ⬤

Indication	SEPSIS
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 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ⬤
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	PANTOPRAZOLE

Prophylaxis

Yes ⚪
No ⚫

Indication	GASTRIC ULCER
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 ⚪

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	9 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	PRILOSEC (OMEPRAZOLE)
Prophylaxis	Yes ⚪
	No ⚫
Indication	GASTRIC ULCER
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 ⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	10 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	DEXTROSE 10%/WATER

Prophylaxis

Yes ●

No ○

Indication	HYPOGLYCEMIA PROPHYLAXIS

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 ○
	Intramuscular ○
	Respiratory (Inhalation) ○
	Intralesional ○
	Intraperiteoneal ○
	Nasal ○
	Vaginal ○
	Rectal ○
	Intravenous ○
	Intravenous Bolus ○
	Intravenous Drip ●
	Other ○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	DEXTROSE 5%/SALINE .9%

Prophylaxis	Yes ◯
	No ●

Indication	INTERMITTENT ELECTROLYTE IMBALANCES

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 ⬭
	Intramuscular ⬭
	Respiratory (Inhalation) ⬭
	Intralesional ⬭
	Intraperiteoneal ⬭
	Nasal ⬭
	Vaginal ⬭
	Rectal ⬭
	Intravenous ⬭
	Intravenous Bolus ⬭
	Intravenous Drip ⬤
	Other ⬭

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	20 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ⬭
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬭

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	HUMULIN R

Prophylaxis

Yes ◯
No ⬤

Indication	DIABETES T2
Dose per administration	VARIABLE

Dose unit

mg ◯
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ⬤

If dose unit is Other, specify	UNITS

Frequency

once daily ◯
twice daily ◯
three times daily ◯
four times daily ⬤
every other day ◯
every week ◯
every month ◯
as needed ◯
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ◯
Topical ◯
Subcutaneous ⬤
Transdermal ◯
Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	27 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	GUAIFENESIN
Prophylaxis	Yes ●
	No ○
Indication	MUCOLYTIC- SUBJ HAD PNEUMONIA
Dose per administration	200
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ●
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	2 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	CARVEDILOL

Prophylaxis	Yes ⬭
	No ⬤

Indication	HYPERTENSION

Dose per administration	12.5

Dose unit	mg ⬤
	ug ⬭
	mL ⬭
	g ⬭
	IU ⬭
	tablet ⬭
	capsule ⬭
	puff ⬭
	Other ⬭

If dose unit is Other, specify	_____

Frequency	once daily ⬭
	twice daily ⬤
	three times daily ⬭
	four times daily ⬭
	every other day ⬭
	every week ⬭
	every month ⬭
	as needed ⬭
	once ⬭
	unknown ⬭
	other ⬭

If frequency is Other, specify	_____

Route of administration	Oral ⬤
	Topical ⬭
	Subcutaneous ⬭
	Transdermal ⬭
	Intraocular ⬭

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	27 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	COMBIVENT NEBULIZER
Prophylaxis	Yes ○
	No ●
Indication	1.) PNEUMONIA
	2.) DYSPNEA
Dose per administration	500/2.5
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	MCG/MG
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	⭕
Intramuscular	⭕
Respiratory (Inhalation)	⬤
Intralesional	⭕
Intraperiteoneal	⭕
Nasal	⭕
Vaginal	⭕
Rectal	⭕
Intravenous	⭕
Intravenous Bolus	⭕
Intravenous Drip	⭕
Other	⭕

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ⭕
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	9 MAR 2021
Was this medication taken for solicited event?	Yes ⭕
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⭕
	803 ⭕
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	HUMULIN 70/30
Prophylaxis	Yes ⚪
	No ⚫
Indication	DIABETES T2
Dose per administration	5
Dose unit	mg ⚪
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚫
If dose unit is Other, specify	UNITS
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 ⚪

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (47)
Data signed: (b) (4) **22 Apr 2021 17:54:05**
Generated On: 09 Jun 2021 15:44:53

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	9 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Name of Medication	ALBUTEROL HFA

Prophylaxis	Yes ⭕
	No ⬤

Indication	DYSPNEA

Dose per administration	90

Dose unit	mg ⭕
	ug ⬤
	mL ⭕
	g ⭕
	IU ⭕
	tablet ⭕
	capsule ⭕
	puff ⭕
	Other ⭕

If dose unit is Other, specify	

Frequency	once daily ⭕
	twice daily ⭕
	three times daily ⭕
	four times daily ⭕
	every other day ⭕
	every week ⭕
	every month ⭕
	as needed ⬤
	once ⭕
	unknown ⭕
	other ⭕

If frequency is Other, specify	

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

	Intramuscular ◯
	Respiratory (Inhalation) ●
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	9 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: [(b) (4)] **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	LISINOPRIL

Prophylaxis	
Yes	◯
No	⬤

Indication	HYPERTENSION
Dose per administration	10

Dose unit	
mg	⬤
ug	◯
mL	◯
g	◯
IU	◯
tablet	◯
capsule	◯
puff	◯
Other	◯

If dose unit is Other, specify _____

Frequency	
once daily	⬤
twice daily	◯
three times daily	◯
four times daily	◯
every other day	◯
every week	◯
every month	◯
as needed	◯
once	◯
unknown	◯
other	◯

If frequency is Other, specify _____

Route of administration	
Oral	⬤
Topical	◯
Subcutaneous	◯
Transdermal	◯
Intraocular	◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (49)
Data signed: (b) (4) **22 Apr 2021 17:54:05**
Generated On: 09 Jun 2021 15:44:53

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	08 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: ▨ (b) (4) ▨ **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	VANCOMYCIN

Prophylaxis

Yes ◯
No ⬤

Indication	SEPSIS
Dose per administration	1250

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 ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	26 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	29 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4)   **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	METRONIDAZOLE

Prophylaxis

- Yes ◯
- No ⬤

Indication	SEPSIS
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 ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (51)
Data signed: (b) (4) **22 Apr 2021 17:54:05**
Generated On: 09 Jun 2021 15:44:53

	Intramuscular ⚪
	Respiratory (Inhalation) ⚪
	Intralesional ⚪
	Intraperiteoneal ⚪
	Nasal ⚪
	Vaginal ⚪
	Rectal ⚪
	Intravenous ⬤
	Intravenous Bolus ⚪
	Intravenous Drip ⚪
	Other ⚪
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⚪
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	24 JAN 2021
Was this medication taken for solicited event?	Yes ⚪
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⚪
	803 ⚪
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	LASIX
Prophylaxis	Yes ⚪
	No ⚫
Indication	LOCULATED ASCITES
Dose per administration	60
Dose unit	mg ⚫
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚫
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⚪
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	28 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	28 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	DIURIL (CHLOROTHIAZIDE)
Prophylaxis	Yes ⚪
	No ⬤
Indication	LOCULATED ASCITES
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 ⚪

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

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	Intramuscular ⬭
	Respiratory (Inhalation) ⬭
	Intralesional ⬭
	Intraperiteoneal ⬭
	Nasal ⬭
	Vaginal ⬭
	Rectal ⬭
	Intravenous ⬤
	Intravenous Bolus ⬭
	Intravenous Drip ⬭
	Other ⬭

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	28 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬤

If not Ongoing, End date *(dd MMM yyyy)*	28 JAN 2021
Was this medication taken for solicited event?	Yes ⬭
	No ⬤

Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬭

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	ZOFRAN
Prophylaxis	Yes ⚪
	No ⚫
Indication	UNSPECIFIED GASTRITIS
Dose per administration	4
Dose unit	mg ⚫
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪
If dose unit is Other, specify	
Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚫
	once ⚪
	unknown ⚪
	other ⚪
If frequency is Other, specify	
Route of administration	Oral ⚪
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	19 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

FDA-CBER-2022-1614-0442279

Name of Medication	ROCEPHIN

Prophylaxis

Yes ⬭
No ⬤

Indication	SEPSIS
Dose per administration	1000

Dose unit

mg ⬤
ug ⬭
mL ⬭
g ⬭
IU ⬭
tablet ⬭
capsule ⬭
puff ⬭
Other ⬭

If dose unit is Other, specify

Frequency

once daily ⬤
twice daily ⬭
three times daily ⬭
four times daily ⬭
every other day ⬭
every week ⬭
every month ⬭
as needed ⬭
once ⬭
unknown ⬭
other ⬭

If frequency is Other, specify

Route of administration

Oral ⬭
Topical ⬭
Subcutaneous ⬭
Transdermal ⬭
Intraocular ⬭

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0442281

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: ▮ (b) (4) ▮ **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	METRONIDAZOLE

Prophylaxis	
Yes	◯
No	⬤

Indication	SEPSIS
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	◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes ◯
	No ●

Indication	SEPSIS
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 ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	●
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	ROCEPHIN

Prophylaxis

Yes ◯

No ⬤

Indication	SEPSIS
Dose per administration	1000

Dose unit

mg ⬤

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify _____

Frequency

once daily ◯

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ⬤

unknown ◯

other ◯

If frequency is Other, specify _____

Route of administration

Oral ◯

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ●
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	NOREPINEPHRINE/ DEXTROSE

Prophylaxis

Yes ⭕
No 🔘

Indication	SEPSIS
Dose per administration	4 MG/ 250

Dose unit

mg ⭕
ug ⭕
mL 🔘
g ⭕
IU ⭕
tablet ⭕
capsule ⭕
puff ⭕
Other ⭕

If dose unit is Other, specify

Frequency

once daily ⭕
twice daily ⭕
three times daily ⭕
four times daily ⭕
every other day ⭕
every week ⭕
every month ⭕
as needed ⭕
once 🔘
unknown ⭕
other ⭕

If frequency is Other, specify

Route of administration

Oral ⭕
Topical ⭕
Subcutaneous ⭕
Transdermal ⭕
Intraocular ⭕

PRODUCTION RELEASE (v12.003
EAB) (1725)

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	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ⬤
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	ALBUTEROL SULFATE

Prophylaxis
Yes ◯
No ⬤

Indication	ACUTE HYPOXIC RESPIRATORY FAILURE

Dose per administration	180

Dose unit
mg ◯
ug ⬤
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency
once daily ◯
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ⬤
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration
Oral ◯
Topical ◯
Subcutaneous ◯
Transdermal ◯

	Intraocular ◯
	Intramuscular ◯
	Respiratory (Inhalation) ⬤
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	HEPARIN SODIUM

Prophylaxis

Yes ●

No ○

Indication	PROPHYLAXIS
Dose per administration	5000

Dose unit

mg ○
ug ○
mL ○
g ○
IU ●
tablet ○
capsule ○
puff ○
Other ○

If dose unit is Other, specify

Frequency

once daily ○
twice daily ○
three times daily ●
four times daily ○
every other day ○
every week ○
every month ○
as needed ○
once ○
unknown ○
other ○

If frequency is Other, specify

Route of administration

Oral ○
Topical ○
Subcutaneous ●
Transdermal ○
Intraocular ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4)   **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	METOPROLOL TARTRATE

Prophylaxis	
	Yes ◯
	No ⬤

Indication	ACUTE RENAL FAILURE
Dose per administration	5

Dose unit	
	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify	

Frequency	
	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ⬤
	unknown ◯
	other ◯

If frequency is Other, specify	

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ●
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	FENOFIBRATE

Prophylaxis	
Yes	○
No	●

Indication	HYPERTRIGLYCERIDEMIA
Dose per administration	145

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	○

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	MIDAZOLAM HCL
Prophylaxis	Yes ◯
	No ⬤
Indication	ACUTE HYPOXIC RESPIRATORY FAILURE
Dose per administration	0.5
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	MG/ML
Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ⬤
If frequency is Other, specify	CONTINUOUS
Route of administration	Oral ◯
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

	Intraocular ⬭
	Intramuscular ⬭
	Respiratory (Inhalation) ⬭
	Intralesional ⬭
	Intraperiteoneal ⬭
	Nasal ⬭
	Vaginal ⬭
	Rectal ⬭
	Intravenous ⬭
	Intravenous Bolus ⬭
	Intravenous Drip ⬛
	Other ⬭

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬛
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ⬭
	No ⬛
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬭

Name of Medication	FENTANYL SODIUM CHLORIDE 20MCG / ML

Prophylaxis	Yes ⬭
	No ⬤

Indication	PANCREATITIS
Dose per administration	20

Dose unit	mg ⬭
	ug ⬭
	mL ⬭
	g ⬭
	IU ⬭
	tablet ⬭
	capsule ⬭
	puff ⬭
	Other ⬤

If dose unit is Other, specify	MCG/ML

Frequency	once daily ⬭
	twice daily ⬭
	three times daily ⬭
	four times daily ⬭
	every other day ⬭
	every week ⬭
	every month ⬭
	as needed ⬭
	once ⬭
	unknown ⬭
	other ⬤

If frequency is Other, specify	CONTINUOUS

Route of administration	Oral ⬭
	Topical ⬭
	Subcutaneous ⬭
	Transdermal ⬭

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Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	⬤
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	MORPHINE SULFATE

Prophylaxis	
Yes	⚪
No	⬤

Indication	PANCREATITIS
Dose per administration	2

Dose unit	
mg	⬤
ug	⚪
mL	⚪
g	⚪
IU	⚪
tablet	⚪
capsule	⚪
puff	⚪
Other	⚪

If dose unit is Other, specify _____

Frequency	
once daily	⚪
twice daily	⚪
three times daily	⚪
four times daily	⚪
every other day	⚪
every week	⚪
every month	⚪
as needed	⚪
once	⬤
unknown	⚪
other	⚪

If frequency is Other, specify _____

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

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EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 22 Apr 2021 17:54:05

Generated On: 09 Jun 2021 15:44:53

Name of Medication	PRECEDEX/NS (DEXMEDETOMIDINE/ SODIUM CHLORIDE 400MCG/ 100 ML

Prophylaxis

Yes ◯
No ⬤

Indication	ACUTE HYPOXIC RESPIRATORY FAILURE

Dose per administration	100

Dose unit

mg ◯
ug ◯
mL ⬤
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ◯
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ⬤
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ◯
Topical ◯
Subcutaneous ◯

Transdermal ◯

Intraocular ◯

Intramuscular ◯

Respiratory (Inhalation) ◯

Intralesional ◯

Intraperiteoneal ◯

Nasal ◯

Vaginal ◯

Rectal ◯

Intravenous ◯

Intravenous Bolus ◯

Intravenous Drip ●

Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	MIDAZOLAM HCL

Prophylaxis

Yes ◯
No ⬤

Indication	ACUTE HYPOXIC RESPIRATORY FAILURE
Dose per administration	2

Dose unit

mg ⬤
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ◯
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ⬤
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ◯
Topical ◯
Subcutaneous ◯
Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	ETOMIDATE

Prophylaxis	Yes ⚪
	No ⚫

Indication	ACUTE HYPOXIC RESPIRATORY FAILURE

Dose per administration	20

Dose unit	mg ⚫
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪

If dose unit is Other, specify	

Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚫
	unknown ⚪
	other ⚪

If frequency is Other, specify	

Route of administration	Oral ⚪
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	DIPRIVAN 1000MG/100ML (PROPOFOL)

Prophylaxis

Yes ◯
No ⬤

Indication	PANCREATITIS
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 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	HYDROMORPHONE HCL

Prophylaxis	Yes ◯
	No ⬤

Indication	PANCREATITIS

Dose per administration	0.5

Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify	

Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ⬤
	once ◯
	unknown ◯
	other ◯

If frequency is Other, specify	

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

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*   15 JAN 2021

Start date completely unknown   False

Ongoing?   Yes ◯
                                                                  No ⬤

If not Ongoing, End date *(dd MMM yyyy)*   16 JAN 2021

Was this medication taken for solicited event?   Yes ◯
                                                                  No ⬤

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived)   802 ◯
                                                                 803 ◯
                                                                 804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	LORAZEPAM
Prophylaxis	Yes ⚪
	No ⚫
Indication	ACUTE HYPOXIC RESPIRATORY FAILURE
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 ⚪

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (72)
Data signed: (b) (4)   **22 Apr 2021 17:54:05**
Generated On: 09 Jun 2021 15:44:53

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	CALCIUM GLUCONATE

Prophylaxis

Yes ◯
No ⬤

Indication	INTERMITTENT ELECTROLYTE IMBALANCE
Dose per administration	4

Dose unit

mg ◯
ug ◯
mL ◯
g ⬤
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ◯
twice daily ◯
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ⬤
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ◯
Topical ◯
Subcutaneous ◯
Transdermal ◯

Intraocular	○
Intramuscular	○
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	●
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	SODIUM PHOSPHATE

Prophylaxis

Yes ⭕

No ⬤

Indication	INTERMITTENT ELECTROLYTE IMBALANCE
Dose per administration	30

Dose unit

mg ⭕
ug ⭕
mL ⭕
g ⭕
IU ⭕
tablet ⭕
capsule ⭕
puff ⭕
Other ⬤

If dose unit is Other, specify	MMOL

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)

FDA-CBER-2022-1614-0442318

Intraocular ⬭

Intramuscular ⬭

Respiratory (Inhalation) ⬭

Intralesional ⬭

Intraperiteoneal ⬭

Nasal ⬭

Vaginal ⬭

Rectal ⬭

Intravenous ⬛

Intravenous Bolus ⬭

Intravenous Drip ⬭

Other ⬭

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⬭
	No ⬛
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ⬭
	No ⬛
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬭

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	POTASSIUM CHLORIDE / DEXTROSE 5% / SODIUM CHLORIDE (POTASSIUM 20 MEQ/LITER; DEXTROSE 1/ NS 2)

Prophylaxis
Yes ◯
No ⬤

Indication	INTERMITTENT ELECTROLYTE
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 ◯

PRODUCTION RELEASE (v12.003 EAB) (1725)

Transdermal	◯
Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	SODIUM CHLORIDE 0.9%
Prophylaxis	Yes ◯
	No ⬤
Indication	INTERMITTENT ELECTROLYTE IMBALANCE
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	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	IODINE SWAB
Prophylaxis	Yes ●
	No ○
Indication	INFECTION PREVENTION
Dose per administration	2
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	SWABS PER NOSTRIL
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 ○

Intramuscular	⚪
Respiratory (Inhalation)	⚪
Intralesional	⚪
Intraperiteoneal	⚪
Nasal	⚫
Vaginal	⚪
Rectal	⚪
Intravenous	⚪
Intravenous Bolus	⚪
Intravenous Drip	⚪
Other	⚪

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ⚪
	No ⚫
If not Ongoing, End date *(dd MMM yyyy)*	16 JAN 2021
Was this medication taken for solicited event?	Yes ⚪
	No ⚫
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⚪
	803 ⚪
	804 ⚫

Name of Medication	CLINIMAX - TOTAL PARENTERAL NUTRITION
Prophylaxis	Yes ○
	No ●
Indication	PANCREATITIS
Dose per administration	VARIED
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	ML/HR
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ●
If frequency is Other, specify	CONTINUOUS
Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○

Intraocular	○
Intramuscular	○
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	●
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	27 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	08 FEB 2021
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	POTASSIUM CHLORIDE
Prophylaxis	Yes ◯
	No ⬤
Indication	INTERMITTENT ELECTROLYTE IMBALANCE
Dose per administration	20
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	MEQ
Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ⬤
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ◯
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	23 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	23 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Name of Medication	SODIUM CHLORIDE 0.9% WEIGHT-BASED

Prophylaxis

Yes ⭕

No ⬤

Indication	INTERMITTENT ELECTROLYTE IMBALANCE

Dose per administration	2863.65

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	○
Intramuscular	○
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	●
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Were any concomitant procedures performed?   Yes ●

                                                    No ○

If yes, please complete Concomitant Procedures form.

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **22 Apr 2021 17:54:05**

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
28 JAN 2021	DECOMPRESSION COLONOSCOPY	Adverse Event	
18 JAN 2021	DIALYSIS	Adverse Event	
17 JAN 2021	INTUBATION	Adverse Event	
17 JAN 2021	MECHANICAL VENTILATION	Adverse Event	
17 JAN 2021	APHORESIS	Adverse Event	
27 JAN 2021	ULTRASOUND GUIDED PARACENTESIS	Adverse Event	

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 _____

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	◯

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) **12 Apr 2021 18:08:40**

Generated On: 09 Jun 2021 15:44:53

SAEID	USA-US128-2021-MRNA-1273-P30 1000010
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

SAEID	USA-US128-2021-MRNA-1273-P30 1000010
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/FEB/2021 15:00
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

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) **12 Apr 2021 18:08:40**

Generated On: 09 Jun 2021 15:44:53

SAEID	USA-US128-2021-MRNA-1273-P30 1000010
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	01/MAR/2021 10:27
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

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: ▒ (b) (4) ▒ **12 Apr 2021 18:08:40**

Generated On: 09 Jun 2021 15:44:53

SAEID	USA-US128-2021-MRNA-1273-P30 1000010
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/MAR/2021 13:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) **12 Apr 2021 18:08:40**

Generated On: 09 Jun 2021 15:44:53

SAEID	USA-US128-2021-MRNA-1273-P30 1000010
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	18/MAR/2021 10:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

SAEID	USA-US128-2021-MRNA-1273-P30 1000010
Serious	Yes ⬤ No ◯
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ◯
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/MAR/2021 09:30
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

SAEID	USA-US128-2021-MRNA-1273-P30 1000010
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/APR/2021 12:20
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

SAEID	USA-US128-2021-MRNA-1273-P30 1000010
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/APR/2021 14:01
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

US3202085 (Prod: WR-ClinSearch, LLC)

US3202085

Form: Participant Creation

Generated On: 09 Jun 2021 15:44:53

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 21:34:42
User entered 'US3202085'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 12:49:10

US3202085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:29

US3202085
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 12:49:11

US3202085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'SCRN'	System	09 Aug 2020 13:05:29

US3202085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered (b) (6) 1980'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 12:49:12

US3202085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:53

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '39'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:44:53
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'YEARS'	System	26 Aug 2020 17:56:02

US3202085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:44:53

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '39'	System	09 Aug 2020 13:05:40

US3202085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:53

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Male (M)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:44:53

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:53

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '1'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:53

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:53

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:53

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:44:53
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:44:53
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:44:53
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:44:53
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:02

US3202085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:53

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:53
User entered '9 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:40

US3202085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:53

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'Aug 2020'	System	09 Aug 2020 13:05:40

US3202085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:53

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '2020'	System	09 Aug 2020 13:05:40

US3202085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:53

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:53
User entered 'Amendment 1 (1)'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:40

US3202085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:53

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:53
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:40

US3202085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:53
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:40

US3202085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:53
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:40

US3202085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:44:53

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:53
User entered 'No (N)'	Tiffany Jewell (b) (4)	09 Aug 2020 13:05:40

US3202085
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:44:53
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 19:38:53
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 12:49:11

US3202085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:53

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '1'	System	09 Aug 2020 13:05:46

US3202085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:44:53

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:46

US3202085

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:44:53

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:56:31

US3202085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:45
Data point term sent to Coder	System	26 Aug 2020 17:58:04
User entered 'seasonal allergies'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:23

US3202085
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:44:53
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '27 Sep 1995'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:23

US3202085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:23

US3202085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:53

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:23

US3202085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:23

US3202085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:23

US3202085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'Sep 1995'	System	26 Aug 2020 17:57:23

US3202085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '1995'	System	26 Aug 2020 17:57:23

US3202085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:53

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	26 Aug 2020 17:57:23

US3202085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:53

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	26 Aug 2020 17:57:23

US3202085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:44
Data point term sent to Coder	System	26 Aug 2020 17:58:05
User entered 'migraines'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:39

US3202085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
	(b) (4)	
User entered '12 Apr 2013'	zackery harmon (b) (4)	26 Aug 2020 17:57:39
	(b) (4)	

US3202085
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:44:53
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:39

US3202085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:53

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:39

US3202085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:39

US3202085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:57:39

US3202085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'Apr 2013'	System	26 Aug 2020 17:57:39

US3202085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '2013'	System	26 Aug 2020 17:57:39

US3202085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:53

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	26 Aug 2020 17:57:39

US3202085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:53

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	26 Aug 2020 17:57:39

US3202085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:44:53
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:46
Data point term sent to Coder	System	26 Aug 2020 17:58:06
User entered 'depression'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:00

US3202085
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:44:53
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '12 Apr 2004'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:00

US3202085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:00

US3202085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:53

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:00

US3202085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:00

US3202085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:00

US3202085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'Apr 2004'	System	26 Aug 2020 17:58:00

US3202085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '2004'	System	26 Aug 2020 17:58:00

US3202085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:53

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	26 Aug 2020 17:58:00

US3202085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:53

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	26 Aug 2020 17:58:00

US3202085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:44:53
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Basedow's disease, LLT: Graves' disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:06:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:06:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
Data point term sent to Coder	System	09 Apr 2021 12:30:07
Coding entries removed.	Erica Osmundsen (b) (4)	09 Apr 2021 12:29:53
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 12:29:53
User entered 'HYPERTHYROIDISM (Grave's Disease)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 12:29:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Hyperthyroidism, LLT: Hyperthyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:50
Data point term sent to Coder	System	26 Aug 2020 17:59:08
User entered 'hyperthyroidism'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:27

US3202085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'un UNK 2017'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:27

US3202085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:27

US3202085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:53

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:27

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US3202085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:27

US3202085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'Jan 2017'	System	26 Aug 2020 17:58:27

US3202085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:44:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '2017'	System	26 Aug 2020 17:58:27

US3202085
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:44:53

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	26 Aug 2020 17:58:27

US3202085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:53

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	26 Aug 2020 17:58:27

US3202085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:44:53
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol abuse, LLT: Alcohol abuse - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 12:40:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 12:40:36
Data point term sent to Coder	System	09 Apr 2021 12:39:17
User entered 'ALCOHOL ABUSE'	Erica Osmundsen (b) (4)	09 Apr 2021 12:38:32

US3202085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
User entered 'UN UNK 2010'	Erica Osmundsen (b) (4)	09 Apr 2021 12:38:32

US3202085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:38:32

US3202085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:44:53
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:38:32

US3202085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:38:32

US3202085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:38:32

US3202085
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:44:53
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'Jan 2010'	System	09 Apr 2021 12:38:32

US3202085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '2010'	System	09 Apr 2021 12:38:32

US3202085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:53

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	09 Apr 2021 12:38:32

US3202085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:53

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered empty.	System	09 Apr 2021 12:38:32

US3202085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:54:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:54:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:47:15
Data point term sent to Coder	System	09 Apr 2021 15:45:58
User entered 'BOTOX FOR MIGRAINES'	Erica Osmundsen (b) (4)	09 Apr 2021 15:45:07

US3202085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:47:15
User entered 'UN UNK 2015'	Erica Osmundsen (b) (4)	09 Apr 2021 15:45:07

US3202085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:47:15
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 15:45:07

US3202085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:53

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:47:15
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 15:45:07

US3202085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:47:15
User entered 'UN UNK 2015'	Erica Osmundsen (b) (4)	09 Apr 2021 15:45:07

US3202085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:47:15
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 15:45:07

US3202085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'Jan 2015'	System	09 Apr 2021 15:45:07

US3202085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '2015'	System	09 Apr 2021 15:45:07

US3202085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:53

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'Jan 2015'	System	09 Apr 2021 15:45:07

US3202085
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:44:53

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '2015'	System	09 Apr 2021 15:45:07

US3202085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35

US3202085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09 Aug 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35

US3202085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09:06'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35

US3202085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered '09 Aug 2020 09:06'	System	26 Aug 2020 18:05:35

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '168.0' cm	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35
DataPoint set to visible.	System	09 Aug 2020 13:05:46

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '94.8' kg	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35
DataPoint set to visible.	System	09 Aug 2020 13:05:46

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
Amendment Manager: User entered '33.58844'	System	16 Sep 2020 23:49:14
User entered '33.6'	System	26 Aug 2020 18:05:35
DataPoint set to visible.	System	09 Aug 2020 13:05:46

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
BMI units

Audit	User	Time (GMT)
Data hard locked.	▮▮ (b) (4), (b) (6) ▮▮	26 Apr 2021 08:56:45
User entered 'kg/m2'	System	26 Aug 2020 18:05:35
DataPoint set to visible.	System	09 Aug 2020 13:05:46

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35

US3202085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 18:05:35

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35

US3202085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'bpm'	System	26 Aug 2020 18:05:35

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'breaths/min'	System	26 Aug 2020 18:05:35

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'mmHg'	System	26 Aug 2020 18:05:35

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:05:35

US3202085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User entered 'mmHg'	System	26 Aug 2020 18:05:35

US3202085
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45

US3202085

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:01:11

US3202085

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:01:11

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:44:53
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:44:53
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

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)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '1'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:44:53
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:00

US3202085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:53

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:56:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 18:02:00
	(b) (4)	

US3202085
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:57

US3202085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09 Aug 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	10 Nov 2020 19:17:33
User entered '9 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:57

US3202085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:05:57

US3202085
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'VISIT1'	System	09 Aug 2020 13:05:57

US3202085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:53

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 13:04:07

US3202085
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:44:53

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:10:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:10:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Aug 2020 13:04:07
User entered '102379' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 13:04:07

US3202085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:53

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 13:04:07

US3202085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:11

US3202085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:11

US3202085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:53

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:11

US3202085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:11

US3202085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:53

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:11

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:44:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09 Aug 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09:06'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '09 Aug 2020 09:06'	System	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '37.3' C	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '66'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'bpm'	System	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '16'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'breaths/min'	System	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '140'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '88'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:44:53
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09 Aug 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '10:22'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '09 Aug 2020 10:22'	System	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '36.7' C	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:44:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '78'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'bpm'	System	26 Aug 2020 18:09:51

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US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '18'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'breaths/min'	System	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '130'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '79'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:09:51

US3202085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	26 Aug 2020 18:09:51

US3202085
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:44:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:21

US3202085
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:44:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09 Aug 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:21

US3202085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:44:09

US3202085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:44:53
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:44:09

US3202085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:44:09

US3202085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:44:53
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'MRNA-1273 OR PLACEBO'	System	09 Aug 2020 13:44:09

US3202085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '9 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:44:09

US3202085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '9:40'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:44:09

US3202085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '9 Aug 2020 9:40'	System	09 Aug 2020 13:44:09

US3202085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	09 Aug 2020 13:44:09

US3202085
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:44:53
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'ONCE'	System	09 Aug 2020 13:44:09

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'INTRAMUSCULAR'	System	09 Aug 2020 13:44:09

US3202085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:41

US3202085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09 Aug 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:41

US3202085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09:10'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:41

Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:44:53
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '09 Aug 2020 09:10'	System	26 Aug 2020 18:02:41

US3202085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:44:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09 Aug 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:51

US3202085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:53

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:51

US3202085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:51

US3202085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:53

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '09:13'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:51

US3202085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '09 Aug 2020 09:13'	System	26 Aug 2020 18:02:51

US3202085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:53

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:51

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:44:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:51

US3202085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:53

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:51

US3202085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered empty.	System	26 Aug 2020 18:02:51

US3202085
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:02:53

US3202085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	26 Aug 2020 18:02:53

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:19:12', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b33a6460-d9f9-4a0a-bebc-6e6f7e44e319'	System	09 Aug 2020 14:20:54
User entered 'Yes (Y)'	System	09 Aug 2020 14:20:54

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:21:03', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b33a6460-d9f9-4a0a-bebc-6e6f7e44e319'	System	09 Aug 2020 14:20:54
User entered '97.8'	System	09 Aug 2020 14:20:54

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:21:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b33a6460-d9f9-4a0a-bebc-6e6f7e44e319'	System	09 Aug 2020 14:20:54
User entered 'No (N)'	System	09 Aug 2020 14:20:54

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:21:14', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b33a6460-d9f9-4a0a-bebc-6e6f7e44e319'	System	09 Aug 2020 14:20:54
User entered '09 Aug 2020 10:21'	System	09 Aug 2020 14:20:54

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '09 Aug 2020 10:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '09 Aug 2020 12:30'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 1, after vaccination (at home)'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:05', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9090ca4c-f726-427f-a38f-a658ea0673f3'	System	09 Aug 2020 17:27:01
User entered 'Yes (Y)'	System	09 Aug 2020 17:27:01

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:13', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9090ca4c-f726-427f-a38f-a658ea0673f3'	System	09 Aug 2020 17:27:01
User entered '97.7'	System	09 Aug 2020 17:27:01

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:18', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9090ca4c-f726-427f-a38f-a658ea0673f3'	System	09 Aug 2020 17:27:01
User entered 'No (N)'	System	09 Aug 2020 17:27:01

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:22', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9090ca4c-f726-427f-a38f-a658ea0673f3'	System	09 Aug 2020 17:27:01
User entered '09 Aug 2020 13:27'	System	09 Aug 2020 17:27:01

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '09 Aug 2020 13:25'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '10 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 2'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:44:53
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:37:27', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ecf3e0cb-aba7-4e4e-8a61-2d49e8073a9c'	System	10 Aug 2020 23:38:15
User entered 'Yes (Y)'	System	10 Aug 2020 23:38:15

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:38:27', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ecf3e0cb-aba7-4e4e-8a61-2d49e8073a9c'	System	10 Aug 2020 23:38:15
User entered '97.9'	System	10 Aug 2020 23:38:15

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:38:34', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ecf3e0cb-aba7-4e4e-8a61-2d49e8073a9c'	System	10 Aug 2020 23:38:15
User entered 'No (N)'	System	10 Aug 2020 23:38:15

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:38:39', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ecf3e0cb-aba7-4e4e-8a61-2d49e8073a9c'	System	10 Aug 2020 23:38:15
User entered '10 Aug 2020 19:38'	System	10 Aug 2020 23:38:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 3'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:33:57', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4dd9f8df-56fb-48c0-8ba6-b76a0e3c890c'	System	11 Aug 2020 18:34:04
User entered 'Yes (Y)'	System	11 Aug 2020 18:34:04

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:34:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4dd9f8df-56fb-48c0-8ba6-b76a0e3c890c'	System	11 Aug 2020 18:34:04
User entered '97.2'	System	11 Aug 2020 18:34:04

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:34:21', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4dd9f8df-56fb-48c0-8ba6-b76a0e3c890c'	System	11 Aug 2020 18:34:04
User entered 'No (N)'	System	11 Aug 2020 18:34:04

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:34:27', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4dd9f8df-56fb-48c0-8ba6-b76a0e3c890c'	System	11 Aug 2020 18:34:04
User entered '11 Aug 2020 14:34'	System	11 Aug 2020 18:34:04

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 4'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:18', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '3ead478c-4f8f-4b73-a64a-196f359a51b9'	System	12 Aug 2020 18:32:10
User entered 'Yes (Y)'	System	12 Aug 2020 18:32:10

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:24', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '3ead478c-4f8f-4b73-a64a-196f359a51b9'	System	12 Aug 2020 18:32:10
User entered '97.6'	System	12 Aug 2020 18:32:10

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:31', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '3ead478c-4f8f-4b73-a64a-196f359a51b9'	System	12 Aug 2020 18:32:10
User entered 'No (N)'	System	12 Aug 2020 18:32:10

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:34', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '3ead478c-4f8f-4b73-a64a-196f359a51b9'	System	12 Aug 2020 18:32:10
User entered '12 Aug 2020 14:32'	System	12 Aug 2020 18:32:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '12 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '13 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 5'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:44:53
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:06', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'a2e0f6c4-0452-4c0b-b9e8-062b9db0cd1c'	System	13 Aug 2020 17:49:52
User entered 'Yes (Y)'	System	13 Aug 2020 17:49:52

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:12', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'a2e0f6c4-0452-4c0b-b9e8-062b9db0cd1c'	System	13 Aug 2020 17:49:52
User entered '98.2'	System	13 Aug 2020 17:49:52

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:15', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'a2e0f6c4-0452-4c0b-b9e8-062b9db0cd1c'	System	13 Aug 2020 17:49:52
User entered 'No (N)'	System	13 Aug 2020 17:49:52

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:18', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'a2e0f6c4-0452-4c0b-b9e8-062b9db0cd1c'	System	13 Aug 2020 17:49:52
User entered '13 Aug 2020 13:50'	System	13 Aug 2020 17:49:52

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '13 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '14 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 6'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:33:19', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '34e81917-770c-4981-b420-82e991d7ba63'	System	14 Aug 2020 16:33:17
User entered 'Yes (Y)'	System	14 Aug 2020 16:33:17

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:33:24', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '34e81917-770c-4981-b420-82e991d7ba63'	System	14 Aug 2020 16:33:17
User entered '98.1'	System	14 Aug 2020 16:33:17

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:33:38', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '34e81917-770c-4981-b420-82e991d7ba63'	System	14 Aug 2020 16:33:17
User entered 'No (N)'	System	14 Aug 2020 16:33:17

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:33:42', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '34e81917-770c-4981-b420-82e991d7ba63'	System	14 Aug 2020 16:33:17
User entered '14 Aug 2020 12:33'	System	14 Aug 2020 16:33:17

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '14 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '15 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 7'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '15 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '16 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:18:37', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '3b3212bf-dd73-4c29-adb3-33a785d4e434'	System	09 Aug 2020 14:21:07
User entered 'None (1)'	System	09 Aug 2020 14:21:07

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:18:40', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '3b3212bf-dd73-4c29-adb3-33a785d4e434'	System	09 Aug 2020 14:21:07
User entered 'No (N)'	System	09 Aug 2020 14:21:07

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:18:43', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '3b3212bf-dd73-4c29-adb3-33a785d4e434'	System	09 Aug 2020 14:21:07
User entered 'No (N)'	System	09 Aug 2020 14:21:07

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:21:24', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '3b3212bf-dd73-4c29-adb3-33a785d4e434'	System	09 Aug 2020 14:21:07
User entered 'None (1)'	System	09 Aug 2020 14:21:07

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:21:30', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '3b3212bf-dd73-4c29-adb3-33a785d4e434'	System	09 Aug 2020 14:21:07
User entered '09 Aug 2020 10:21'	System	09 Aug 2020 14:21:07

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '09 Aug 2020 10:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '09 Aug 2020 12:30'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 1, after vaccination (at home)'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:27', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b6b54689-809e-42df-9db0-c4145f0c782b'	System	09 Aug 2020 17:27:17
User entered 'None (1)'	System	09 Aug 2020 17:27:17

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:31', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b6b54689-809e-42df-9db0-c4145f0c782b'	System	09 Aug 2020 17:27:17
User entered 'No (N)'	System	09 Aug 2020 17:27:17

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:33', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b6b54689-809e-42df-9db0-c4145f0c782b'	System	09 Aug 2020 17:27:17
User entered 'No (N)'	System	09 Aug 2020 17:27:17

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:36', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b6b54689-809e-42df-9db0-c4145f0c782b'	System	09 Aug 2020 17:27:17
User entered 'None (1)'	System	09 Aug 2020 17:27:17

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:40', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b6b54689-809e-42df-9db0-c4145f0c782b'	System	09 Aug 2020 17:27:17
User entered '09 Aug 2020 13:27'	System	09 Aug 2020 17:27:17

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '09 Aug 2020 13:25'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '10 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 2'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:38:43', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'af1649cc-2dbf-4c8d-a7ae-f1645b9efaa4'	System	10 Aug 2020 23:38:32
User entered 'None (1)'	System	10 Aug 2020 23:38:32

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:38:47', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'af1649cc-2dbf-4c8d-a7ae-f1645b9efaa4'	System	10 Aug 2020 23:38:32
User entered 'No (N)'	System	10 Aug 2020 23:38:32

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:44:53
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:38:49', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'af1649cc-2dbf-4c8d-a7ae-f1645b9efaa4'	System	10 Aug 2020 23:38:32
User entered 'No (N)'	System	10 Aug 2020 23:38:32

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:38:51', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'af1649cc-2dbf-4c8d-a7ae-f1645b9efaa4'	System	10 Aug 2020 23:38:32
User entered 'None (1)'	System	10 Aug 2020 23:38:32

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:38:55', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'af1649cc-2dbf-4c8d-a7ae-f1645b9efaa4'	System	10 Aug 2020 23:38:32
User entered '10 Aug 2020 19:38'	System	10 Aug 2020 23:38:32

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 3'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:34:32', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'dfbdf0ec-2cc1-42c2-8e37-832b3045dad1'	System	11 Aug 2020 18:34:21
User entered 'None (1)'	System	11 Aug 2020 18:34:21

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:34:36', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'dfbdf0ec-2cc1-42c2-8e37-832b3045dad1'	System	11 Aug 2020 18:34:21
User entered 'No (N)'	System	11 Aug 2020 18:34:21

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:44:53
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:34:38', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'dfbdf0ec-2cc1-42c2-8e37-832b3045dad1'	System	11 Aug 2020 18:34:21
User entered 'No (N)'	System	11 Aug 2020 18:34:21

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:34:40', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'dfbdf0ec-2cc1-42c2-8e37-832b3045dad1'	System	11 Aug 2020 18:34:21
User entered 'None (1)'	System	11 Aug 2020 18:34:21

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:34:43', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'dfbdf0ec-2cc1-42c2-8e37-832b3045dad1'	System	11 Aug 2020 18:34:21
User entered '11 Aug 2020 14:34'	System	11 Aug 2020 18:34:21

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 4'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:39', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '46c9e459-a56e-4d0b-b6d0-c03c21c480f2'	System	12 Aug 2020 18:32:25
User entered 'None (1)'	System	12 Aug 2020 18:32:25

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:41', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '46c9e459-a56e-4d0b-b6d0-c03c21c480f2'	System	12 Aug 2020 18:32:25
User entered 'No (N)'	System	12 Aug 2020 18:32:25

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:43', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '46c9e459-a56e-4d0b-b6d0-c03c21c480f2'	System	12 Aug 2020 18:32:25
User entered 'No (N)'	System	12 Aug 2020 18:32:25

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:46', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '46c9e459-a56e-4d0b-b6d0-c03c21c480f2'	System	12 Aug 2020 18:32:25
User entered 'None (1)'	System	12 Aug 2020 18:32:25

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:49', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '46c9e459-a56e-4d0b-b6d0-c03c21c480f2'	System	12 Aug 2020 18:32:25
User entered '12 Aug 2020 14:32'	System	12 Aug 2020 18:32:25

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '12 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '13 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 5'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:23', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '72c435cc-2d98-47ac-9405-efea801e719c'	System	13 Aug 2020 17:50:09
User entered 'None (1)'	System	13 Aug 2020 17:50:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:27', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '72c435cc-2d98-47ac-9405-efea801e719c'	System	13 Aug 2020 17:50:09
User entered 'No (N)'	System	13 Aug 2020 17:50:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:44:53
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:29', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '72c435cc-2d98-47ac-9405-efea801e719c'	System	13 Aug 2020 17:50:09
User entered 'No (N)'	System	13 Aug 2020 17:50:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:31', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '72c435cc-2d98-47ac-9405-efea801e719c'	System	13 Aug 2020 17:50:09
User entered 'None (1)'	System	13 Aug 2020 17:50:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:34', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '72c435cc-2d98-47ac-9405-efea801e719c'	System	13 Aug 2020 17:50:09
User entered '13 Aug 2020 13:50'	System	13 Aug 2020 17:50:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '13 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '14 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 6'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:33:49', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'eb235735-8c1f-4c1e-b0d3-fefedcf73367'	System	14 Aug 2020 16:33:36
User entered 'None (1)'	System	14 Aug 2020 16:33:36

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:33:52', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'eb235735-8c1f-4c1e-b0d3-fefedcf73367'	System	14 Aug 2020 16:33:36
User entered 'No (N)'	System	14 Aug 2020 16:33:36

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:33:55', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'eb235735-8c1f-4c1e-b0d3-fefedcf73367'	System	14 Aug 2020 16:33:36
User entered 'No (N)'	System	14 Aug 2020 16:33:36

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:33:57', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'eb235735-8c1f-4c1e-b0d3-fefedcf73367'	System	14 Aug 2020 16:33:36
User entered 'None (1)'	System	14 Aug 2020 16:33:36

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:34:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'eb235735-8c1f-4c1e-b0d3-fefedcf73367'	System	14 Aug 2020 16:33:36
User entered '14 Aug 2020 12:34'	System	14 Aug 2020 16:33:36

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '14 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '15 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 7'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

FDA-CBER-2022-1614-0442675

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '15 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '16 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:21:58', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'bf3805ad-5324-4278-b02a-62ae42fe0149'	System	09 Aug 2020 14:22:40
User entered 'None (0)'	System	09 Aug 2020 14:22:40

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:22:07', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'bf3805ad-5324-4278-b02a-62ae42fe0149'	System	09 Aug 2020 14:22:40
User entered 'None (0)'	System	09 Aug 2020 14:22:40

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:22:12', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'bf3805ad-5324-4278-b02a-62ae42fe0149'	System	09 Aug 2020 14:22:40
User entered 'None (0)'	System	09 Aug 2020 14:22:40

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:22:17', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'bf3805ad-5324-4278-b02a-62ae42fe0149'	System	09 Aug 2020 14:22:40
User entered 'None (0)'	System	09 Aug 2020 14:22:40

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:22:22', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'bf3805ad-5324-4278-b02a-62ae42fe0149'	System	09 Aug 2020 14:22:40
User entered 'None (0)'	System	09 Aug 2020 14:22:40

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:22:25', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'bf3805ad-5324-4278-b02a-62ae42fe0149'	System	09 Aug 2020 14:22:40
User entered 'None (0)'	System	09 Aug 2020 14:22:40

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:22:35', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'bf3805ad-5324-4278-b02a-62ae42fe0149'	System	09 Aug 2020 14:22:40
User entered 'No (N)'	System	09 Aug 2020 14:22:40

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T10:23:04', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'bf3805ad-5324-4278-b02a-62ae42fe0149'	System	09 Aug 2020 14:22:40
User entered '09 Aug 2020 10:23'	System	09 Aug 2020 14:22:40

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '09 Aug 2020 10:00'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '09 Aug 2020 12:30'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 1, after vaccination (at home)'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:46', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd2d0d5de-4ecd-4b4b-926f-c48f31f429d0'	System	09 Aug 2020 17:27:45
User entered 'None (0)'	System	09 Aug 2020 17:27:45

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:48', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd2d0d5de-4ecd-4b4b-926f-c48f31f429d0'	System	09 Aug 2020 17:27:45
User entered 'None (0)'	System	09 Aug 2020 17:27:45

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:51', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd2d0d5de-4ecd-4b4b-926f-c48f31f429d0'	System	09 Aug 2020 17:27:45
User entered 'None (0)'	System	09 Aug 2020 17:27:45

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:53', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd2d0d5de-4ecd-4b4b-926f-c48f31f429d0'	System	09 Aug 2020 17:27:45
User entered 'None (0)'	System	09 Aug 2020 17:27:45

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:55', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd2d0d5de-4ecd-4b4b-926f-c48f31f429d0'	System	09 Aug 2020 17:27:45
User entered 'None (0)'	System	09 Aug 2020 17:27:45

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:27:58', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd2d0d5de-4ecd-4b4b-926f-c48f31f429d0'	System	09 Aug 2020 17:27:45
User entered 'None (0)'	System	09 Aug 2020 17:27:45

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:28:06', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd2d0d5de-4ecd-4b4b-926f-c48f31f429d0'	System	09 Aug 2020 17:27:45
User entered 'No (N)'	System	09 Aug 2020 17:27:45

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-09T13:28:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd2d0d5de-4ecd-4b4b-926f-c48f31f429d0'	System	09 Aug 2020 17:27:45
User entered '09 Aug 2020 13:28'	System	09 Aug 2020 17:27:45

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '09 Aug 2020 13:25'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '10 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 2'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:39:03', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1ce6ed68-a7ed-448c-9a31-18c7f8cb4405'	System	10 Aug 2020 23:39:02
User entered 'None (0)'	System	10 Aug 2020 23:39:02

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:39:05', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1ce6ed68-a7ed-448c-9a31-18c7f8cb4405'	System	10 Aug 2020 23:39:02
User entered 'None (0)'	System	10 Aug 2020 23:39:02

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:39:08', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1ce6ed68-a7ed-448c-9a31-18c7f8cb4405'	System	10 Aug 2020 23:39:02
User entered 'None (0)'	System	10 Aug 2020 23:39:02

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:39:12', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1ce6ed68-a7ed-448c-9a31-18c7f8cb4405'	System	10 Aug 2020 23:39:02
User entered 'None (0)'	System	10 Aug 2020 23:39:02

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:39:15', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1ce6ed68-a7ed-448c-9a31-18c7f8cb4405'	System	10 Aug 2020 23:39:02
User entered 'None (0)'	System	10 Aug 2020 23:39:02

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:39:17', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1ce6ed68-a7ed-448c-9a31-18c7f8cb4405'	System	10 Aug 2020 23:39:02
User entered 'None (0)'	System	10 Aug 2020 23:39:02

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:39:23', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1ce6ed68-a7ed-448c-9a31-18c7f8cb4405'	System	10 Aug 2020 23:39:02
User entered 'No (N)'	System	10 Aug 2020 23:39:02

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-10T19:39:26', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1ce6ed68-a7ed-448c-9a31-18c7f8cb4405'	System	10 Aug 2020 23:39:02
User entered '10 Aug 2020 19:39'	System	10 Aug 2020 23:39:02

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 3'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:35:37', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9a7407e2-1da9-4624-bb17-1b73b9a837a6'	System	11 Aug 2020 18:35:44
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	11 Aug 2020 18:35:44

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:35:40', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9a7407e2-1da9-4624-bb17-1b73b9a837a6'	System	11 Aug 2020 18:35:44
User entered 'None (0)'	System	11 Aug 2020 18:35:44

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:35:43', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9a7407e2-1da9-4624-bb17-1b73b9a837a6'	System	11 Aug 2020 18:35:44
User entered 'None (0)'	System	11 Aug 2020 18:35:44

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:35:45', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9a7407e2-1da9-4624-bb17-1b73b9a837a6'	System	11 Aug 2020 18:35:44
User entered 'None (0)'	System	11 Aug 2020 18:35:44

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:35:47', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9a7407e2-1da9-4624-bb17-1b73b9a837a6'	System	11 Aug 2020 18:35:44
User entered 'None (0)'	System	11 Aug 2020 18:35:44

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:35:51', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9a7407e2-1da9-4624-bb17-1b73b9a837a6'	System	11 Aug 2020 18:35:44
User entered 'None (0)'	System	11 Aug 2020 18:35:44

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:36:06', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9a7407e2-1da9-4624-bb17-1b73b9a837a6'	System	11 Aug 2020 18:35:44
User entered 'No (N)'	System	11 Aug 2020 18:35:44

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-11T14:36:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9a7407e2-1da9-4624-bb17-1b73b9a837a6'	System	11 Aug 2020 18:35:44
User entered '11 Aug 2020 14:36'	System	11 Aug 2020 18:35:44

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 4'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:54', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4b8c278f-e611-4f5d-bdad-9a1238da3ba8'	System	12 Aug 2020 18:32:47
User entered 'None (0)'	System	12 Aug 2020 18:32:47

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:56', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4b8c278f-e611-4f5d-bdad-9a1238da3ba8'	System	12 Aug 2020 18:32:47
User entered 'None (0)'	System	12 Aug 2020 18:32:47

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:32:59', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4b8c278f-e611-4f5d-bdad-9a1238da3ba8'	System	12 Aug 2020 18:32:47
User entered 'None (0)'	System	12 Aug 2020 18:32:47

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:33:01', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4b8c278f-e611-4f5d-bdad-9a1238da3ba8'	System	12 Aug 2020 18:32:47
User entered 'None (0)'	System	12 Aug 2020 18:32:47

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:33:03', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4b8c278f-e611-4f5d-bdad-9a1238da3ba8'	System	12 Aug 2020 18:32:47
User entered 'None (0)'	System	12 Aug 2020 18:32:47

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:33:07', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4b8c278f-e611-4f5d-bdad-9a1238da3ba8'	System	12 Aug 2020 18:32:47
User entered 'None (0)'	System	12 Aug 2020 18:32:47

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:33:10', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4b8c278f-e611-4f5d-bdad-9a1238da3ba8'	System	12 Aug 2020 18:32:47
User entered 'No (N)'	System	12 Aug 2020 18:32:47

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-12T14:33:12', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4b8c278f-e611-4f5d-bdad-9a1238da3ba8'	System	12 Aug 2020 18:32:47
User entered '12 Aug 2020 14:33'	System	12 Aug 2020 18:32:47

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '12 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '13 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 5'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:39', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1e6126c9-68a2-4425-b3f7-eb7f3078fba5'	System	13 Aug 2020 17:50:31
User entered 'None (0)'	System	13 Aug 2020 17:50:31

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:41', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1e6126c9-68a2-4425-b3f7-eb7f3078fba5'	System	13 Aug 2020 17:50:31
User entered 'None (0)'	System	13 Aug 2020 17:50:31

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:44', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1e6126c9-68a2-4425-b3f7-eb7f3078fba5'	System	13 Aug 2020 17:50:31
User entered 'None (0)'	System	13 Aug 2020 17:50:31

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:46', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1e6126c9-68a2-4425-b3f7-eb7f3078fba5'	System	13 Aug 2020 17:50:31
User entered 'None (0)'	System	13 Aug 2020 17:50:31

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:48', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1e6126c9-68a2-4425-b3f7-eb7f3078fba5'	System	13 Aug 2020 17:50:31
User entered 'None (0)'	System	13 Aug 2020 17:50:31

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:50', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1e6126c9-68a2-4425-b3f7-eb7f3078fba5'	System	13 Aug 2020 17:50:31
User entered 'None (0)'	System	13 Aug 2020 17:50:31

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:53', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1e6126c9-68a2-4425-b3f7-eb7f3078fba5'	System	13 Aug 2020 17:50:31
User entered 'No (N)'	System	13 Aug 2020 17:50:31

FDA-CBER-2022-1614-0442744

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-13T13:50:56', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1e6126c9-68a2-4425-b3f7-eb7f3078fba5'	System	13 Aug 2020 17:50:31
User entered '13 Aug 2020 13:50'	System	13 Aug 2020 17:50:31

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '13 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '14 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 6'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:34:04', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1326f0de-5f50-4d34-8eb2-98ff029d3ce2'	System	14 Aug 2020 16:34:03
User entered 'None (0)'	System	14 Aug 2020 16:34:03

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:34:07', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1326f0de-5f50-4d34-8eb2-98ff029d3ce2'	System	14 Aug 2020 16:34:03
User entered 'None (0)'	System	14 Aug 2020 16:34:03

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:34:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1326f0de-5f50-4d34-8eb2-98ff029d3ce2'	System	14 Aug 2020 16:34:03
User entered 'None (0)'	System	14 Aug 2020 16:34:03

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:34:13', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1326f0de-5f50-4d34-8eb2-98ff029d3ce2'	System	14 Aug 2020 16:34:03
User entered 'None (0)'	System	14 Aug 2020 16:34:03

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:34:20', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1326f0de-5f50-4d34-8eb2-98ff029d3ce2'	System	14 Aug 2020 16:34:03
User entered 'None (0)'	System	14 Aug 2020 16:34:03

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:34:22', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1326f0de-5f50-4d34-8eb2-98ff029d3ce2'	System	14 Aug 2020 16:34:03
User entered 'None (0)'	System	14 Aug 2020 16:34:03

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:34:25', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1326f0de-5f50-4d34-8eb2-98ff029d3ce2'	System	14 Aug 2020 16:34:03
User entered 'No (N)'	System	14 Aug 2020 16:34:03

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-08-14T12:34:28', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1326f0de-5f50-4d34-8eb2-98ff029d3ce2'	System	14 Aug 2020 16:34:03
User entered '14 Aug 2020 12:34'	System	14 Aug 2020 16:34:03

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '14 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '15 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 7'	System	09 Aug 2020 13:44:09

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '15 Aug 2020 12:00'	System	09 Aug 2020 13:44:09

US3202085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '16 Aug 2020 11:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:10:27

US3202085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '17 Aug 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:10:27

Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:10:27

FDA-CBER-2022-1614-0442772

US3202085
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:10:27

US3202085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:10:31

US3202085
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:44:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	26 Aug 2020 18:10:31

US3202085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	10 Oct 2020 18:16:28

US3202085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Oct 2020 18:17:06
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	10 Oct 2020 18:17:06
User entered '23 Aug 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	10 Oct 2020 18:17:06
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Oct 2020 18:16:28
User entered '23 Sep 2020'	zackery harmon (b) (4) (b) (4)	10 Oct 2020 18:16:28

US3202085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	zackery harmon (b) (4) (b) (4)	10 Oct 2020 18:16:28

US3202085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'attempts x3'	zackery harmon (b) (4) (b) (4)	10 Oct 2020 18:16:28

US3202085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 18:45:26

US3202085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	18 Sep 2020 18:45:26

US3202085
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	10 Oct 2020 18:17:21

US3202085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '30 Aug 2020'	zackery harmon (b) (4) (b) (4)	10 Oct 2020 18:17:21

US3202085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	zackery harmon (b) (4) (b) (4)	10 Oct 2020 18:17:21

US3202085
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'attempts x3'	zackery harmon (b) (4) (b) (4)	10 Oct 2020 18:17:21

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 18:45:34

US3202085
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:44:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	18 Sep 2020 18:45:34

US3202085
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User closed query 'Per CDM: Please complete remaining V2 forms. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:56:45
Query 'Per CDM: Please complete remaining V2 forms. ' answered with 'Fields updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 15:03:59
User opened query 'Per CDM: Please complete remaining V2 forms. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:26:26
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 17:15:15

US3202085
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 17:26:04
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Date is correct' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 17:16:45
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Sep 2020 17:15:15
User entered '18 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 17:15:15

US3202085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 17:15:15

US3202085
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'VISIT2'	System	26 Sep 2020 17:15:15

US3202085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '18 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '14:15'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '18 Sep 2020 14:15'	System	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '37.1' C	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '82'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'bpm'	System	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '18'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'breaths/min'	System	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '118'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '83'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	07 Oct 2020 14:55:47

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US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '18 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '15:29'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

FDA-CBER-2022-1614-0442811

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '18 Sep 2020 15:29'	System	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '36.9' C	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

FDA-CBER-2022-1614-0442815

US3202085
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:44:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '66'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'bpm'	System	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '16'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'breaths/min'	System	07 Oct 2020 14:55:47

FDA-CBER-2022-1614-0442819

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '136'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '89'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:55:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	07 Oct 2020 14:55:47

US3202085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 17:16:52

US3202085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 17:16:52

US3202085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User closed query 'Per CDM: V2 D29 Study treatment was given to the patient and "VISIT DATE form is blank, please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:50:01
Query 'Per CDM: V2 D29 Study treatment was given to the patient and "VISIT DATE" form is blank, please review and update accordingly ' answered with 'Fields updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	26 Sep 2020 17:17:30
User opened query 'Per CDM: V2 D29 Study treatment was given to the patient and "VISIT DATE form is blank, please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 15:21:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 18:46:04

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 18:46:04

US3202085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:46:04

US3202085
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 18:46:04

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' canceled (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:05:15
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:04:36
User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:10:26
Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' answered with 'OOW-Scheduling conflict between site and subject' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 13:41:57
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:09:05
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 18:46:04

US3202085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered '14:32'	(b) (4), (b) (6)	18 Sep 2020 18:46:04

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '18 Sep 2020 14:32'	System	18 Sep 2020 18:46:04

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	18 Sep 2020 18:46:04

US3202085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'ONCE'	System	18 Sep 2020 18:46:04

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 18:46:04

US3202085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:06

US3202085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '18 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:06

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '14:24'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:06

FDA-CBER-2022-1614-0442838

US3202085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '18 Sep 2020 14:24'	System	07 Oct 2020 14:56:06

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:44:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '18 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:18

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:53

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:18

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:18

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:53

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '14:22'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:18

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '18 Sep 2020 14:22'	System	07 Oct 2020 14:56:18

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:53

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:18

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:18

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:53

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 14:56:18

US3202085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered empty.	System	07 Oct 2020 14:56:18

US3202085
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	25 Sep 2020 17:02:27

US3202085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	25 Sep 2020 17:02:27

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:30:42', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ae900910-10bb-48cd-91f9-88e4726e1e7b'	System	18 Sep 2020 19:31:09
User entered 'Yes (Y)'	System	18 Sep 2020 19:31:09

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:31:23', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ae900910-10bb-48cd-91f9-88e4726e1e7b'	System	18 Sep 2020 19:31:09
User entered '98.4'	System	18 Sep 2020 19:31:09

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:31:30', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ae900910-10bb-48cd-91f9-88e4726e1e7b'	System	18 Sep 2020 19:31:09
User entered 'No (N)'	System	18 Sep 2020 19:31:09

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:31:36', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ae900910-10bb-48cd-91f9-88e4726e1e7b'	System	18 Sep 2020 19:31:09
User entered '18 Sep 2020 15:31'	System	18 Sep 2020 19:31:09

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '18 Sep 2020 14:52'	System	18 Sep 2020 18:46:04

FDA-CBER-2022-1614-0442856

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '18 Sep 2020 17:22'	System	18 Sep 2020 18:46:04

FDA-CBER-2022-1614-0442857

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T19:22:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e0b80424-4479-459c-8fd5-05045e97188c'	System	18 Sep 2020 23:21:26
User entered 'Yes (Y)'	System	18 Sep 2020 23:21:26

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T19:22:05', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e0b80424-4479-459c-8fd5-05045e97188c'	System	18 Sep 2020 23:21:26
User entered '98.5'	System	18 Sep 2020 23:21:26

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T19:22:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e0b80424-4479-459c-8fd5-05045e97188c'	System	18 Sep 2020 23:21:26
User entered 'No (N)'	System	18 Sep 2020 23:21:26

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T19:22:12', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e0b80424-4479-459c-8fd5-05045e97188c'	System	18 Sep 2020 23:21:26
User entered '18 Sep 2020 19:22'	System	18 Sep 2020 23:21:26

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '18 Sep 2020 18:17'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 2'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:00:50', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '29fd932d-5818-4857-930d-5cec3de7f704'	System	19 Sep 2020 16:00:23
User entered 'Yes (Y)'	System	19 Sep 2020 16:00:23

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:00:57', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '29fd932d-5818-4857-930d-5cec3de7f704'	System	19 Sep 2020 16:00:23
User entered '98.2'	System	19 Sep 2020 16:00:23

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:01', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '29fd932d-5818-4857-930d-5cec3de7f704'	System	19 Sep 2020 16:00:23
User entered 'No (N)'	System	19 Sep 2020 16:00:23

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:04', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '29fd932d-5818-4857-930d-5cec3de7f704'	System	19 Sep 2020 16:00:23
User entered '19 Sep 2020 12:01'	System	19 Sep 2020 16:00:23

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 3'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:47', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '336c7abf-e77c-45b9-98c2-7ebd20be4320'	System	20 Sep 2020 16:05:14
User entered 'Yes (Y)'	System	20 Sep 2020 16:05:14

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:54', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '336c7abf-e77c-45b9-98c2-7ebd20be4320'	System	20 Sep 2020 16:05:14
User entered '97.9'	System	20 Sep 2020 16:05:14

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:58', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '336c7abf-e77c-45b9-98c2-7ebd20be4320'	System	20 Sep 2020 16:05:14
User entered 'No (N)'	System	20 Sep 2020 16:05:14

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:06:01', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '336c7abf-e77c-45b9-98c2-7ebd20be4320'	System	20 Sep 2020 16:05:14
User entered '20 Sep 2020 12:06'	System	20 Sep 2020 16:05:14

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 4'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:51:16', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fa78ec82-9711-4286-8659-936255601cb9'	System	21 Sep 2020 16:50:46
User entered 'Yes (Y)'	System	21 Sep 2020 16:50:46

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:51:22', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fa78ec82-9711-4286-8659-936255601cb9'	System	21 Sep 2020 16:50:46
User entered '97.1'	System	21 Sep 2020 16:50:46

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:51:25', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fa78ec82-9711-4286-8659-936255601cb9'	System	21 Sep 2020 16:50:46
User entered 'No (N)'	System	21 Sep 2020 16:50:46

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:51:28', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fa78ec82-9711-4286-8659-936255601cb9'	System	21 Sep 2020 16:50:46
User entered '21 Sep 2020 12:51'	System	21 Sep 2020 16:50:46

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 5'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:08', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c237ae9b-6c72-4be9-a7dc-10c4a1b90ad2'	System	23 Sep 2020 04:11:34
User entered 'Yes (Y)'	System	23 Sep 2020 04:11:34

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:13', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c237ae9b-6c72-4be9-a7dc-10c4a1b90ad2'	System	23 Sep 2020 04:11:34
User entered '97.2'	System	23 Sep 2020 04:11:34

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:18', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c237ae9b-6c72-4be9-a7dc-10c4a1b90ad2'	System	23 Sep 2020 04:11:34
User entered 'No (N)'	System	23 Sep 2020 04:11:34

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:21', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c237ae9b-6c72-4be9-a7dc-10c4a1b90ad2'	System	23 Sep 2020 04:11:34
User entered '23 Sep 2020 00:12'	System	23 Sep 2020 04:11:34

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 6'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:01:53', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c9afeeba-f894-4532-8441-614386beb953'	System	23 Sep 2020 17:04:02
User entered 'Yes (Y)'	System	23 Sep 2020 17:04:02

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:01:58', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c9afeeba-f894-4532-8441-614386beb953'	System	23 Sep 2020 17:04:02
User entered '97.3'	System	23 Sep 2020 17:04:02

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:01', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c9afeeba-f894-4532-8441-614386beb953'	System	23 Sep 2020 17:04:02
User entered 'No (N)'	System	23 Sep 2020 17:04:02

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:04', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c9afeeba-f894-4532-8441-614386beb953'	System	23 Sep 2020 17:04:02
User entered '23 Sep 2020 13:02'	System	23 Sep 2020 17:04:02

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 7'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:52:49', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e336aaed-9de2-4f3a-8d6a-eb38b8262701'	System	24 Sep 2020 16:52:16
User entered 'Yes (Y)'	System	24 Sep 2020 16:52:16

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:52:58', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e336aaed-9de2-4f3a-8d6a-eb38b8262701'	System	24 Sep 2020 16:52:16
User entered '97.0'	System	24 Sep 2020 16:52:16

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:02', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e336aaed-9de2-4f3a-8d6a-eb38b8262701'	System	24 Sep 2020 16:52:16
User entered 'No (N)'	System	24 Sep 2020 16:52:16

US3202085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:05', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e336aaed-9de2-4f3a-8d6a-eb38b8262701'	System	24 Sep 2020 16:52:16
User entered '24 Sep 2020 12:53'	System	24 Sep 2020 16:52:16

US3202085
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:44:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

FDA-CBER-2022-1614-0442906

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:31:41', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '8f2afe5b-36fc-4a87-b57c-3b197f5c39eb'	System	18 Sep 2020 19:31:13
User entered 'None (1)'	System	18 Sep 2020 19:31:13

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:31:45', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '8f2afe5b-36fc-4a87-b57c-3b197f5c39eb'	System	18 Sep 2020 19:31:13
User entered 'No (N)'	System	18 Sep 2020 19:31:13

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:31:47', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '8f2afe5b-36fc-4a87-b57c-3b197f5c39eb'	System	18 Sep 2020 19:31:13
User entered 'No (N)'	System	18 Sep 2020 19:31:13

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:31:50', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '8f2afe5b-36fc-4a87-b57c-3b197f5c39eb'	System	18 Sep 2020 19:31:13
User entered 'None (1)'	System	18 Sep 2020 19:31:13

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:31:53', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '8f2afe5b-36fc-4a87-b57c-3b197f5c39eb'	System	18 Sep 2020 19:31:13
User entered '18 Sep 2020 15:31'	System	18 Sep 2020 19:31:13

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '18 Sep 2020 14:52'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '18 Sep 2020 17:22'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:58:24', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ec957205-b0ae-45f5-a0bc-9ef17864b0b7'	System	18 Sep 2020 22:58:28
User entered 'None (1)'	System	18 Sep 2020 22:58:28

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:58:30', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ec957205-b0ae-45f5-a0bc-9ef17864b0b7'	System	18 Sep 2020 22:58:28
User entered 'No (N)'	System	18 Sep 2020 22:58:28

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:58:40', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ec957205-b0ae-45f5-a0bc-9ef17864b0b7'	System	18 Sep 2020 22:58:28
User entered 'No (N)'	System	18 Sep 2020 22:58:28

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:58:49', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ec957205-b0ae-45f5-a0bc-9ef17864b0b7'	System	18 Sep 2020 22:58:28
User entered 'None (1)'	System	18 Sep 2020 22:58:28

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:59:13', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'ec957205-b0ae-45f5-a0bc-9ef17864b0b7'	System	18 Sep 2020 22:58:28
User entered '18 Sep 2020 18:59'	System	18 Sep 2020 22:58:28

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '18 Sep 2020 18:17'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 2'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd5a2be1a-6721-4788-9eae-82bcfec28430'	System	19 Sep 2020 16:00:34
User entered 'None (1)'	System	19 Sep 2020 16:00:34

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US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:13', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd5a2be1a-6721-4788-9eae-82bcfec28430'	System	19 Sep 2020 16:00:34
User entered 'No (N)'	System	19 Sep 2020 16:00:34

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:15', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd5a2be1a-6721-4788-9eae-82bcfec28430'	System	19 Sep 2020 16:00:34
User entered 'No (N)'	System	19 Sep 2020 16:00:34

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:17', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd5a2be1a-6721-4788-9eae-82bcfec28430'	System	19 Sep 2020 16:00:34
User entered 'None (1)'	System	19 Sep 2020 16:00:34

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:20', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd5a2be1a-6721-4788-9eae-82bcfec28430'	System	19 Sep 2020 16:00:34
User entered '19 Sep 2020 12:01'	System	19 Sep 2020 16:00:34

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

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PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

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US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 3'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:20', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'acd6105d-b8dc-4e24-8a78-5ebe8f78f755'	System	20 Sep 2020 16:04:54
User entered 'None (1)'	System	20 Sep 2020 16:04:54

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:23', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'acd6105d-b8dc-4e24-8a78-5ebe8f78f755'	System	20 Sep 2020 16:04:54
User entered 'No (N)'	System	20 Sep 2020 16:04:54

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:32', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'acd6105d-b8dc-4e24-8a78-5ebe8f78f755'	System	20 Sep 2020 16:04:54
User entered 'No (N)'	System	20 Sep 2020 16:04:54

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:34', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'acd6105d-b8dc-4e24-8a78-5ebe8f78f755'	System	20 Sep 2020 16:04:54
User entered 'None (1)'	System	20 Sep 2020 16:04:54

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:41', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'acd6105d-b8dc-4e24-8a78-5ebe8f78f755'	System	20 Sep 2020 16:04:54
User entered '20 Sep 2020 12:05'	System	20 Sep 2020 16:04:54

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:44:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 4'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:52', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '5ec3cade-dde5-424f-9d86-af5796833ae3'	System	21 Sep 2020 16:50:35
User entered 'None (1)'	System	21 Sep 2020 16:50:35

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:56', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '5ec3cade-dde5-424f-9d86-af5796833ae3'	System	21 Sep 2020 16:50:35
User entered 'No (N)'	System	21 Sep 2020 16:50:35

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:58', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '5ec3cade-dde5-424f-9d86-af5796833ae3'	System	21 Sep 2020 16:50:35
User entered 'No (N)'	System	21 Sep 2020 16:50:35

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:51:02', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '5ec3cade-dde5-424f-9d86-af5796833ae3'	System	21 Sep 2020 16:50:35
User entered 'None (1)'	System	21 Sep 2020 16:50:35

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:51:08', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '5ec3cade-dde5-424f-9d86-af5796833ae3'	System	21 Sep 2020 16:50:35
User entered '21 Sep 2020 12:51'	System	21 Sep 2020 16:50:35

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 5'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:26', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9ba8e1ed-8cce-4a55-a402-a7b56e352bf8'	System	23 Sep 2020 04:11:48
User entered 'None (1)'	System	23 Sep 2020 04:11:48

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:29', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9ba8e1ed-8cce-4a55-a402-a7b56e352bf8'	System	23 Sep 2020 04:11:48
User entered 'No (N)'	System	23 Sep 2020 04:11:48

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:32', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9ba8e1ed-8cce-4a55-a402-a7b56e352bf8'	System	23 Sep 2020 04:11:48
User entered 'No (N)'	System	23 Sep 2020 04:11:48

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:34', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9ba8e1ed-8cce-4a55-a402-a7b56e352bf8'	System	23 Sep 2020 04:11:48
User entered 'None (1)'	System	23 Sep 2020 04:11:48

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:37', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9ba8e1ed-8cce-4a55-a402-a7b56e352bf8'	System	23 Sep 2020 04:11:48
User entered '23 Sep 2020 00:12'	System	23 Sep 2020 04:11:48

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

FDA-CBER-2022-1614-0442954

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 6'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0786912b-e05b-442c-9f47-2860deb23717'	System	23 Sep 2020 17:05:17
User entered 'None (1)'	System	23 Sep 2020 17:05:17

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:21', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0786912b-e05b-442c-9f47-2860deb23717'	System	23 Sep 2020 17:05:17
User entered 'No (N)'	System	23 Sep 2020 17:05:17

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:44:53
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:24', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0786912b-e05b-442c-9f47-2860deb23717'	System	23 Sep 2020 17:05:17
User entered 'No (N)'	System	23 Sep 2020 17:05:17

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:27', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0786912b-e05b-442c-9f47-2860deb23717'	System	23 Sep 2020 17:05:17
User entered 'None (1)'	System	23 Sep 2020 17:05:17

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:29', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0786912b-e05b-442c-9f47-2860deb23717'	System	23 Sep 2020 17:05:17
User entered '23 Sep 2020 13:02'	System	23 Sep 2020 17:05:17

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 7'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:53

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:10', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fe009457-1963-459f-b99a-86ea34d8fbe7'	System	24 Sep 2020 16:52:31
User entered 'None (1)'	System	24 Sep 2020 16:52:31

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:12', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fe009457-1963-459f-b99a-86ea34d8fbe7'	System	24 Sep 2020 16:52:31
User entered 'No (N)'	System	24 Sep 2020 16:52:31

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:15', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fe009457-1963-459f-b99a-86ea34d8fbe7'	System	24 Sep 2020 16:52:31
User entered 'No (N)'	System	24 Sep 2020 16:52:31

US3202085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:17', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fe009457-1963-459f-b99a-86ea34d8fbe7'	System	24 Sep 2020 16:52:31
User entered 'None (1)'	System	24 Sep 2020 16:52:31

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:20', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fe009457-1963-459f-b99a-86ea34d8fbe7'	System	24 Sep 2020 16:52:31
User entered '24 Sep 2020 12:53'	System	24 Sep 2020 16:52:31

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:32:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1afdb93e-aeef-4bd4-9673-786207b941e7'	System	18 Sep 2020 19:31:35
User entered 'None (0)'	System	18 Sep 2020 19:31:35

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:32:03', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1afdb93e-aeef-4bd4-9673-786207b941e7'	System	18 Sep 2020 19:31:35
User entered 'None (0)'	System	18 Sep 2020 19:31:35

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:32:06', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1afdb93e-aeef-4bd4-9673-786207b941e7'	System	18 Sep 2020 19:31:35
User entered 'None (0)'	System	18 Sep 2020 19:31:35

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:32:08', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1afdb93e-aeef-4bd4-9673-786207b941e7'	System	18 Sep 2020 19:31:35
User entered 'None (0)'	System	18 Sep 2020 19:31:35

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:32:11', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1afdb93e-aeef-4bd4-9673-786207b941e7'	System	18 Sep 2020 19:31:35
User entered 'None (0)'	System	18 Sep 2020 19:31:35

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:32:14', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1afdb93e-aeef-4bd4-9673-786207b941e7'	System	18 Sep 2020 19:31:35
User entered 'None (0)'	System	18 Sep 2020 19:31:35

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:32:18', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1afdb93e-aeef-4bd4-9673-786207b941e7'	System	18 Sep 2020 19:31:35
User entered 'No (N)'	System	18 Sep 2020 19:31:35

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T15:32:21', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1afdb93e-aeef-4bd4-9673-786207b941e7'	System	18 Sep 2020 19:31:35
User entered '18 Sep 2020 15:32'	System	18 Sep 2020 19:31:35

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '18 Sep 2020 14:52'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '18 Sep 2020 17:22'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:56:58', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4a961d93-aca6-4870-b28e-414df6491461'	System	18 Sep 2020 22:57:19
User entered 'None (0)'	System	18 Sep 2020 22:57:19

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:57:04', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4a961d93-aca6-4870-b28e-414df6491461'	System	18 Sep 2020 22:57:19
User entered 'None (0)'	System	18 Sep 2020 22:57:19

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:57:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4a961d93-aca6-4870-b28e-414df6491461'	System	18 Sep 2020 22:57:19
User entered 'None (0)'	System	18 Sep 2020 22:57:19

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:57:14', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4a961d93-aca6-4870-b28e-414df6491461'	System	18 Sep 2020 22:57:19
User entered 'None (0)'	System	18 Sep 2020 22:57:19

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:57:17', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4a961d93-aca6-4870-b28e-414df6491461'	System	18 Sep 2020 22:57:19
User entered 'None (0)'	System	18 Sep 2020 22:57:19

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:57:49', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4a961d93-aca6-4870-b28e-414df6491461'	System	18 Sep 2020 22:57:19
User entered 'Some interference with activity not requiring medical attention (2)'	System	18 Sep 2020 22:57:19

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:58:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4a961d93-aca6-4870-b28e-414df6491461'	System	18 Sep 2020 22:57:19
User entered 'No (N)'	System	18 Sep 2020 22:57:19

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-18T18:58:04', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4a961d93-aca6-4870-b28e-414df6491461'	System	18 Sep 2020 22:57:19
User entered '18 Sep 2020 18:58'	System	18 Sep 2020 22:57:19

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '18 Sep 2020 18:17'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:44:53
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 2'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:25', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '95149863-064d-4bdc-9e05-49d26026e14b'	System	19 Sep 2020 16:01:09
User entered 'None (0)'	System	19 Sep 2020 16:01:09

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:27', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '95149863-064d-4bdc-9e05-49d26026e14b'	System	19 Sep 2020 16:01:09
User entered 'None (0)'	System	19 Sep 2020 16:01:09

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:30', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '95149863-064d-4bdc-9e05-49d26026e14b'	System	19 Sep 2020 16:01:09
User entered 'None (0)'	System	19 Sep 2020 16:01:09

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:32', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '95149863-064d-4bdc-9e05-49d26026e14b'	System	19 Sep 2020 16:01:09
User entered 'None (0)'	System	19 Sep 2020 16:01:09

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:34', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '95149863-064d-4bdc-9e05-49d26026e14b'	System	19 Sep 2020 16:01:09
User entered 'None (0)'	System	19 Sep 2020 16:01:09

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:36', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '95149863-064d-4bdc-9e05-49d26026e14b'	System	19 Sep 2020 16:01:09
User entered 'None (0)'	System	19 Sep 2020 16:01:09

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:40', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '95149863-064d-4bdc-9e05-49d26026e14b'	System	19 Sep 2020 16:01:09
User entered 'No (N)'	System	19 Sep 2020 16:01:09

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-19T12:01:42', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '95149863-064d-4bdc-9e05-49d26026e14b'	System	19 Sep 2020 16:01:09
User entered '19 Sep 2020 12:01'	System	19 Sep 2020 16:01:09

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

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US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 3'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:04:47', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '40ecf6e4-6a98-4743-acaf-1aa7aec997a7'	System	20 Sep 2020 16:04:32
User entered 'None (0)'	System	20 Sep 2020 16:04:32

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:04:51', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '40ecf6e4-6a98-4743-acaf-1aa7aec997a7'	System	20 Sep 2020 16:04:32
User entered 'None (0)'	System	20 Sep 2020 16:04:32

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:04:53', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '40ecf6e4-6a98-4743-acaf-1aa7aec997a7'	System	20 Sep 2020 16:04:32
User entered 'None (0)'	System	20 Sep 2020 16:04:32

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:04:58', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '40ecf6e4-6a98-4743-acaf-1aa7aec997a7'	System	20 Sep 2020 16:04:32
User entered 'None (0)'	System	20 Sep 2020 16:04:32

FDA-CBER-2022-1614-0443008

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:01', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '40ecf6e4-6a98-4743-acaf-1aa7aec997a7'	System	20 Sep 2020 16:04:32
User entered 'None (0)'	System	20 Sep 2020 16:04:32

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:04', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '40ecf6e4-6a98-4743-acaf-1aa7aec997a7'	System	20 Sep 2020 16:04:32
User entered 'None (0)'	System	20 Sep 2020 16:04:32

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:06', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '40ecf6e4-6a98-4743-acaf-1aa7aec997a7'	System	20 Sep 2020 16:04:32
User entered 'No (N)'	System	20 Sep 2020 16:04:32

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-20T12:05:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '40ecf6e4-6a98-4743-acaf-1aa7aec997a7'	System	20 Sep 2020 16:04:32
User entered '20 Sep 2020 12:05'	System	20 Sep 2020 16:04:32

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 4'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:30', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b34fd90-8c42-4e70-b36c-31e630491745'	System	21 Sep 2020 16:50:25
User entered 'None (0)'	System	21 Sep 2020 16:50:25

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:33', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b34fd90-8c42-4e70-b36c-31e630491745'	System	21 Sep 2020 16:50:25
User entered 'None (0)'	System	21 Sep 2020 16:50:25

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:35', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b34fd90-8c42-4e70-b36c-31e630491745'	System	21 Sep 2020 16:50:25
User entered 'None (0)'	System	21 Sep 2020 16:50:25

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:37', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b34fd90-8c42-4e70-b36c-31e630491745'	System	21 Sep 2020 16:50:25
User entered 'None (0)'	System	21 Sep 2020 16:50:25

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:39', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b34fd90-8c42-4e70-b36c-31e630491745'	System	21 Sep 2020 16:50:25
User entered 'None (0)'	System	21 Sep 2020 16:50:25

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:42', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b34fd90-8c42-4e70-b36c-31e630491745'	System	21 Sep 2020 16:50:25
User entered 'None (0)'	System	21 Sep 2020 16:50:25

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:45', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b34fd90-8c42-4e70-b36c-31e630491745'	System	21 Sep 2020 16:50:25
User entered 'No (N)'	System	21 Sep 2020 16:50:25

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-21T12:50:48', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b34fd90-8c42-4e70-b36c-31e630491745'	System	21 Sep 2020 16:50:25
User entered '21 Sep 2020 12:50'	System	21 Sep 2020 16:50:25

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 5'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:11:36', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1618d314-f3d2-478d-994b-4e0c2db444b7'	System	23 Sep 2020 04:11:14
User entered 'None (0)'	System	23 Sep 2020 04:11:14

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:11:38', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1618d314-f3d2-478d-994b-4e0c2db444b7'	System	23 Sep 2020 04:11:14
User entered 'None (0)'	System	23 Sep 2020 04:11:14

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:11:40', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1618d314-f3d2-478d-994b-4e0c2db444b7'	System	23 Sep 2020 04:11:14
User entered 'None (0)'	System	23 Sep 2020 04:11:14

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US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:11:44', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1618d314-f3d2-478d-994b-4e0c2db444b7'	System	23 Sep 2020 04:11:14
User entered 'None (0)'	System	23 Sep 2020 04:11:14

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:11:46', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1618d314-f3d2-478d-994b-4e0c2db444b7'	System	23 Sep 2020 04:11:14
User entered 'None (0)'	System	23 Sep 2020 04:11:14

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:11:48', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1618d314-f3d2-478d-994b-4e0c2db444b7'	System	23 Sep 2020 04:11:14
User entered 'None (0)'	System	23 Sep 2020 04:11:14

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:11:51', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1618d314-f3d2-478d-994b-4e0c2db444b7'	System	23 Sep 2020 04:11:14
User entered 'No (N)'	System	23 Sep 2020 04:11:14

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T00:12:01', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '1618d314-f3d2-478d-994b-4e0c2db444b7'	System	23 Sep 2020 04:11:14
User entered '23 Sep 2020 00:12'	System	23 Sep 2020 04:11:14

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 6'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:34', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '04ab9f06-a9ab-4773-bd5d-106e2648f0b1'	System	23 Sep 2020 17:05:45
User entered 'None (0)'	System	23 Sep 2020 17:05:45

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:36', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '04ab9f06-a9ab-4773-bd5d-106e2648f0b1'	System	23 Sep 2020 17:05:45
User entered 'None (0)'	System	23 Sep 2020 17:05:45

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:38', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '04ab9f06-a9ab-4773-bd5d-106e2648f0b1'	System	23 Sep 2020 17:05:45
User entered 'None (0)'	System	23 Sep 2020 17:05:45

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:41', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '04ab9f06-a9ab-4773-bd5d-106e2648f0b1'	System	23 Sep 2020 17:05:45
User entered 'None (0)'	System	23 Sep 2020 17:05:45

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:43', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '04ab9f06-a9ab-4773-bd5d-106e2648f0b1'	System	23 Sep 2020 17:05:45
User entered 'None (0)'	System	23 Sep 2020 17:05:45

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:45', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '04ab9f06-a9ab-4773-bd5d-106e2648f0b1'	System	23 Sep 2020 17:05:45
User entered 'None (0)'	System	23 Sep 2020 17:05:45

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:47', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '04ab9f06-a9ab-4773-bd5d-106e2648f0b1'	System	23 Sep 2020 17:05:45
User entered 'No (N)'	System	23 Sep 2020 17:05:45

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-23T13:02:50', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '04ab9f06-a9ab-4773-bd5d-106e2648f0b1'	System	23 Sep 2020 17:05:45
User entered '23 Sep 2020 13:02'	System	23 Sep 2020 17:05:45

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	18 Sep 2020 18:46:04
User entered 'Day 7'	System	18 Sep 2020 18:46:04

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:25', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '02bd616e-dd63-4f4c-b071-b2278a64c8f4'	System	24 Sep 2020 16:52:52
User entered 'None (0)'	System	24 Sep 2020 16:52:52

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:27', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '02bd616e-dd63-4f4c-b071-b2278a64c8f4'	System	24 Sep 2020 16:52:52
User entered 'None (0)'	System	24 Sep 2020 16:52:52

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:29', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '02bd616e-dd63-4f4c-b071-b2278a64c8f4'	System	24 Sep 2020 16:52:52
User entered 'None (0)'	System	24 Sep 2020 16:52:52

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:31', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '02bd616e-dd63-4f4c-b071-b2278a64c8f4'	System	24 Sep 2020 16:52:52
User entered 'None (0)'	System	24 Sep 2020 16:52:52

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:33', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '02bd616e-dd63-4f4c-b071-b2278a64c8f4'	System	24 Sep 2020 16:52:52
User entered 'None (0)'	System	24 Sep 2020 16:52:52

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:35', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '02bd616e-dd63-4f4c-b071-b2278a64c8f4'	System	24 Sep 2020 16:52:52
User entered 'None (0)'	System	24 Sep 2020 16:52:52

US3202085
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:44:53
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:39', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '02bd616e-dd63-4f4c-b071-b2278a64c8f4'	System	24 Sep 2020 16:52:52
User entered 'No (N)'	System	24 Sep 2020 16:52:52

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:53

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-09-24T12:53:41', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '02bd616e-dd63-4f4c-b071-b2278a64c8f4'	System	24 Sep 2020 16:52:52
User entered '24 Sep 2020 12:53'	System	24 Sep 2020 16:52:52

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:46:04

US3202085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:53

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:46:04

US3202085
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	25 Sep 2020 17:02:40

US3202085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '25 Sep 2020'	Lilian Nukuna (b) (4) (b) (4)	25 Sep 2020 17:02:40

US3202085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	25 Sep 2020 17:02:40

US3202085
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	25 Sep 2020 17:02:40

US3202085
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	25 Sep 2020 17:02:48

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	25 Sep 2020 17:02:48

US3202085
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 15:03:20

US3202085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 13:50:56
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct ' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 15:03:31
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Oct 2020 15:03:20
User entered '1 Oct 2020'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 15:03:20

Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Contact Made (CONTACT MADE)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 15:03:20

US3202085
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 15:03:20

US3202085
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 15:03:36

US3202085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	07 Oct 2020 15:03:36

US3202085
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	09 Oct 2020 20:08:47

US3202085
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '9 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	09 Oct 2020 20:08:47

US3202085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	09 Oct 2020 20:08:47

US3202085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	09 Oct 2020 20:08:47

US3202085
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	09 Oct 2020 20:08:52

US3202085
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:44:53
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	09 Oct 2020 20:08:52

US3202085
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	30 Oct 2020 15:33:55

US3202085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 16:19:37
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'schedule conflict between subject & site' (Site from System).	Teresa Deese (b) (4)	30 Oct 2020 15:34:14
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Oct 2020 15:33:55
User entered '30 Oct 2020'	Teresa Deese (b) (4)	30 Oct 2020 15:33:55

US3202085
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	30 Oct 2020 15:33:55

US3202085
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'VISIT3'	System	30 Oct 2020 15:33:55

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '30 Oct 2020'	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

FDA-CBER-2022-1614-0443082

US3202085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered '10:34'	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

US3202085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '30 Oct 2020 10:34'	System	30 Oct 2020 15:38:12

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered '36.4' C	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

US3202085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '73'	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'bpm'	System	30 Oct 2020 15:38:12

US3202085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered '16'	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'breaths/min'	System	30 Oct 2020 15:38:12

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered '155'	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	30 Oct 2020 15:38:12

FDA-CBER-2022-1614-0443093

US3202085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 14:58:51
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Teresa Deese (b) (4)	30 Oct 2020 15:38:26
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Oct 2020 15:38:12
User entered '104'	Teresa Deese (b) (4)	30 Oct 2020 15:38:12

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered 'mmHg'	System	30 Oct 2020 15:38:12

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49

US3202085
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:44:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49

US3202085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'No (N)'	Teresa Deese (b) (4)	30 Oct 2020 15:38:33

US3202085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:38:33

US3202085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	30 Oct 2020 15:38:47

US3202085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered '30 Oct 2020'	Teresa Deese (b) (4)	30 Oct 2020 15:38:47

Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:44:53
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 01:55:28
User entered '10:51'	Teresa Deese (b) (4)	30 Oct 2020 15:38:47

US3202085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '30 Oct 2020 10:51'	System	30 Oct 2020 15:38:47

US3202085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 01:55:28
User entered 'Yes (Y)'	Teresa Deese (b) (4)	30 Oct 2020 15:38:58

US3202085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	30 Oct 2020 15:38:58

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 64'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-10-09T00:09:12', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e1eced4a-b85e-4a4c-baab-a5369297a53d'	System	09 Oct 2020 04:08:29
User entered 'No (N)'	System	09 Oct 2020 04:08:29

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-10-09T00:09:23', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e1eced4a-b85e-4a4c-baab-a5369297a53d'	System	09 Oct 2020 04:08:29
User entered 'No (N)'	System	09 Oct 2020 04:08:29

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-10-09T00:09:29', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'e1eced4a-b85e-4a4c-baab-a5369297a53d'	System	09 Oct 2020 04:08:29
User entered '09 Oct 2020 00:09:29'	System	09 Oct 2020 04:08:29

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '09 Oct 2020 00:01'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '13 Oct 2020 23:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 71'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '16 Oct 2020 00:01'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:47:18
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '20 Oct 2020 23:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 78'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-10-23T02:40:55', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0bb04ebe-9554-43db-8b49-4991b2d55020'	System	23 Oct 2020 06:40:29
User entered 'No (N)'	System	23 Oct 2020 06:40:29

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-10-23T02:41:30', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0bb04ebe-9554-43db-8b49-4991b2d55020'	System	23 Oct 2020 06:40:29
User entered 'No (N)'	System	23 Oct 2020 06:40:29

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-10-23T02:41:36', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0bb04ebe-9554-43db-8b49-4991b2d55020'	System	23 Oct 2020 06:40:29
User entered '23 Oct 2020 02:41:36'	System	23 Oct 2020 06:40:29

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '23 Oct 2020 00:01'	System	09 Aug 2020 13:44:09

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '27 Oct 2020 23:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 92'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-11-06T00:01:41', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4f0159e2-7c4c-460e-a642-084e5001b6ea'	System	06 Nov 2020 05:00:33
User entered 'No (N)'	System	06 Nov 2020 05:00:33

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-11-06T00:01:46', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4f0159e2-7c4c-460e-a642-084e5001b6ea'	System	06 Nov 2020 05:00:33
User entered 'No (N)'	System	06 Nov 2020 05:00:33

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-11-06T00:01:52', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '4f0159e2-7c4c-460e-a642-084e5001b6ea'	System	06 Nov 2020 05:00:33
User entered '06 Nov 2020 00:01:52'	System	06 Nov 2020 05:00:33

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '06 Nov 2020 00:01'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '10 Nov 2020 23:59'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered 'Day 99'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-11-13T00:06:06', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '8a2777d4-6da9-4316-a809-3118cb65ed42'	System	13 Nov 2020 05:04:49
User entered 'No (N)'	System	13 Nov 2020 05:04:49

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-11-13T00:06:10', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '8a2777d4-6da9-4316-a809-3118cb65ed42'	System	13 Nov 2020 05:04:49
User entered 'No (N)'	System	13 Nov 2020 05:04:49

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-11-13T00:06:15', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '8a2777d4-6da9-4316-a809-3118cb65ed42'	System	13 Nov 2020 05:04:49
User entered '13 Nov 2020 00:06:15'	System	13 Nov 2020 05:04:49

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '13 Nov 2020 00:01'	System	09 Aug 2020 13:44:09

US3202085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:25:28
Data entry locked.	System	09 Aug 2020 13:44:09
User entered '17 Nov 2020 23:59'	System	09 Aug 2020 13:44:09

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (55863ade400859df)', Time: '2020-11-19T19:18:55', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd0051be1-e339-4b40-bd3f-d899aa94c98a'	System	20 Nov 2020 00:19:06
User entered 'No (N)'	System	20 Nov 2020 00:19:06

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (55863ade400859df)', Time: '2020-11-19T19:19:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd0051be1-e339-4b40-bd3f-d899aa94c98a'	System	20 Nov 2020 00:19:06
User entered 'No (N)'	System	20 Nov 2020 00:19:06

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-11-19T19:19:03', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'd0051be1-e339-4b40-bd3f-d899aa94c98a'	System	20 Nov 2020 00:19:06
User entered '19 Nov 2020 19:19:03'	System	20 Nov 2020 00:19:06

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (55863ade400859df)', Time: '2020-11-24T00:01:36', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '63ee2d59-f1ec-4086-b947-59edf7ae3c88'	System	24 Nov 2020 05:02:14
User entered 'No (N)'	System	24 Nov 2020 05:02:14

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (55863ade400859df)', Time: '2020-11-24T00:01:40', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '63ee2d59-f1ec-4086-b947-59edf7ae3c88'	System	24 Nov 2020 05:02:14
User entered 'No (N)'	System	24 Nov 2020 05:02:14

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-11-24T00:02:10', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '63ee2d59-f1ec-4086-b947-59edf7ae3c88'	System	24 Nov 2020 05:02:14
User entered '24 Nov 2020 00:02:10'	System	24 Nov 2020 05:02:14

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (55863ade400859df)', Time: '2020-12-01T00:01:29', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b37d41b0-edc4-48b4-94a2-dd5aae7f619e'	System	01 Dec 2020 05:01:44
User entered 'No (N)'	System	01 Dec 2020 05:01:44

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (55863ade400859df)', Time: '2020-12-01T00:01:34', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b37d41b0-edc4-48b4-94a2-dd5aae7f619e'	System	01 Dec 2020 05:01:44
User entered 'No (N)'	System	01 Dec 2020 05:01:44

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-12-01T00:01:38', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'b37d41b0-edc4-48b4-94a2-dd5aae7f619e'	System	01 Dec 2020 05:01:44
User entered '01 Dec 2020 00:01:38'	System	01 Dec 2020 05:01:44

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (55863ade400859df)', Time: '2020-12-08T13:20:56', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b33272b-c74c-44b5-9dd6-dd6839701bca'	System	08 Dec 2020 18:21:12
User entered 'No (N)'	System	08 Dec 2020 18:21:12

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (55863ade400859df)', Time: '2020-12-08T13:21:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b33272b-c74c-44b5-9dd6-dd6839701bca'	System	08 Dec 2020 18:21:12
User entered 'No (N)'	System	08 Dec 2020 18:21:12

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-12-08T13:21:03', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '2b33272b-c74c-44b5-9dd6-dd6839701bca'	System	08 Dec 2020 18:21:12
User entered '08 Dec 2020 13:21:03'	System	08 Dec 2020 18:21:12

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (55863ade400859df)', Time: '2020-12-15T19:04:09', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '44e0a915-ca77-4eb4-9686-748882264c3b'	System	16 Dec 2020 00:04:20
User entered 'No (N)'	System	16 Dec 2020 00:04:20

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (55863ade400859df)', Time: '2020-12-15T19:04:12', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '44e0a915-ca77-4eb4-9686-748882264c3b'	System	16 Dec 2020 00:04:20
User entered 'No (N)'	System	16 Dec 2020 00:04:20

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-12-15T19:04:15', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '44e0a915-ca77-4eb4-9686-748882264c3b'	System	16 Dec 2020 00:04:20
User entered '15 Dec 2020 19:04:15'	System	16 Dec 2020 00:04:20

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 16:47:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:47:18

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US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (55863ade400859df)', Time: '2020-12-22T01:26:54', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'db36cb0c-7b73-49bf-a75c-5bfd766d9006'	System	22 Dec 2020 06:27:13
User entered 'No (N)'	System	22 Dec 2020 06:27:13

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (55863ade400859df)', Time: '2020-12-22T01:26:58', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'db36cb0c-7b73-49bf-a75c-5bfd766d9006'	System	22 Dec 2020 06:27:13
User entered 'No (N)'	System	22 Dec 2020 06:27:13

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-12-22T01:27:06', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'db36cb0c-7b73-49bf-a75c-5bfd766d9006'	System	22 Dec 2020 06:27:13
User entered '22 Dec 2020 01:27:06'	System	22 Dec 2020 06:27:13

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (55863ade400859df)', Time: '2020-12-29T00:01:48', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'f34f0b00-a878-4258-83f8-273a996c396a'	System	29 Dec 2020 05:02:02
User entered 'No (N)'	System	29 Dec 2020 05:02:02

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (55863ade400859df)', Time: '2020-12-29T00:01:52', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'f34f0b00-a878-4258-83f8-273a996c396a'	System	29 Dec 2020 05:02:02
User entered 'No (N)'	System	29 Dec 2020 05:02:02

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55863ade400859df)', Time: '2020-12-29T00:01:55', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'f34f0b00-a878-4258-83f8-273a996c396a'	System	29 Dec 2020 05:02:02
User entered '29 Dec 2020 00:01:55'	System	29 Dec 2020 05:02:02

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-03-05T09:11:20-05:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c68c4791-9f4c-4407-aedc-66f200ecae48'	System	05 Mar 2021 14:11:21
User entered 'No (N)'	System	05 Mar 2021 14:11:21

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-03-05T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c68c4791-9f4c-4407-aedc-66f200ecae48'	System	05 Mar 2021 14:11:21
User entered 'No (N)'	System	05 Mar 2021 14:11:21

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-03-05T09:11:26-05:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c68c4791-9f4c-4407-aedc-66f200ecae48'	System	05 Mar 2021 14:11:21
User entered '05 Mar 2021 09:11:26'	System	05 Mar 2021 14:11:21

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-03-09T01:38:42-05:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '563a4764-ba0f-4bdb-8b57-347761b25c65'	System	09 Mar 2021 06:38:43
User entered 'No (N)'	System	09 Mar 2021 06:38:43

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-03-09T01:38:45-05:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '563a4764-ba0f-4bdb-8b57-347761b25c65'	System	09 Mar 2021 06:38:43
User entered 'No (N)'	System	09 Mar 2021 06:38:43

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-03-09T01:38:49-05:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '563a4764-ba0f-4bdb-8b57-347761b25c65'	System	09 Mar 2021 06:38:43
User entered '09 Mar 2021 01:38:49'	System	09 Mar 2021 06:38:43

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-03-16T00:01:42-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c3494b65-932c-4b5a-9c1d-c0651debde83'	System	16 Mar 2021 04:02:50
User entered 'No (N)'	System	16 Mar 2021 04:02:50

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-03-16T00:01:46-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c3494b65-932c-4b5a-9c1d-c0651debde83'	System	16 Mar 2021 04:02:50
User entered 'No (N)'	System	16 Mar 2021 04:02:50

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-03-16T00:01:49-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'c3494b65-932c-4b5a-9c1d-c0651debde83'	System	16 Mar 2021 04:02:50
User entered '16 Mar 2021 00:01:49'	System	16 Mar 2021 04:02:50

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 16:47:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-03-23T00:05:20-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '684f6c64-23f6-46c7-9384-dad3d7d62fe2'	System	23 Mar 2021 04:05:45
User entered 'No (N)'	System	23 Mar 2021 04:05:45

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-03-23T00:05:25-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '684f6c64-23f6-46c7-9384-dad3d7d62fe2'	System	23 Mar 2021 04:05:45
User entered 'No (N)'	System	23 Mar 2021 04:05:45

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-03-23T00:05:28-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '684f6c64-23f6-46c7-9384-dad3d7d62fe2'	System	23 Mar 2021 04:05:45
User entered '23 Mar 2021 00:05:28'	System	23 Mar 2021 04:05:45

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-03-30T23:51:33-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'efd0c268-786a-4d00-90d4-0b1e27054506'	System	31 Mar 2021 03:52:00
User entered 'No (N)'	System	31 Mar 2021 03:52:00

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-03-30T23:51:36-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'efd0c268-786a-4d00-90d4-0b1e27054506'	System	31 Mar 2021 03:52:00
User entered 'No (N)'	System	31 Mar 2021 03:52:00

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-03-30T23:51:38-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'efd0c268-786a-4d00-90d4-0b1e27054506'	System	31 Mar 2021 03:52:00
User entered '30 Mar 2021 23:51:38'	System	31 Mar 2021 03:52:00

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-04-07T12:07:48-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '347a2f69-a10d-4997-bce0-df9370335db4'	System	07 Apr 2021 16:16:14
User entered 'No (N)'	System	07 Apr 2021 16:16:14

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-04-07T12:07:51-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '347a2f69-a10d-4997-bce0-df9370335db4'	System	07 Apr 2021 16:16:14
User entered 'No (N)'	System	07 Apr 2021 16:16:14

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-04-07T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '347a2f69-a10d-4997-bce0-df9370335db4'	System	07 Apr 2021 16:16:14
User entered '07 Apr 2021 12:07:54'	System	07 Apr 2021 16:16:14

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 16:47:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 16:47:18

FDA-CBER-2022-1614-0443259

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-04-13T23:30:25-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0b35c33c-91ea-44a4-b3ee-afc0c2dad0bc'	System	14 Apr 2021 03:30:31
User entered 'No (N)'	System	14 Apr 2021 03:30:31

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-04-13T23:30:27-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0b35c33c-91ea-44a4-b3ee-afc0c2dad0bc'	System	14 Apr 2021 03:30:31
User entered 'No (N)'	System	14 Apr 2021 03:30:31

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-04-13T23:30:30-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '0b35c33c-91ea-44a4-b3ee-afc0c2dad0bc'	System	14 Apr 2021 03:30:31
User entered '13 Apr 2021 23:30:30'	System	14 Apr 2021 03:30:31

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-04-20T10:15:51-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'f246e4b3-8183-42ac-9c31-d0445d791b31'	System	20 Apr 2021 14:15:50
User entered 'No (N)'	System	20 Apr 2021 14:15:50

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-04-20T10:15:54-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'f246e4b3-8183-42ac-9c31-d0445d791b31'	System	20 Apr 2021 14:15:50
User entered 'No (N)'	System	20 Apr 2021 14:15:50

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-04-20T10:15:57-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'f246e4b3-8183-42ac-9c31-d0445d791b31'	System	20 Apr 2021 14:15:50
User entered '20 Apr 2021 10:15:57'	System	20 Apr 2021 14:15:50

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-04-27T00:08:50-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9fa477cb-e9df-4609-88b0-3180a2ab8527'	System	27 Apr 2021 04:08:52
User entered 'No (N)'	System	27 Apr 2021 04:08:52

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-04-27T00:08:52-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9fa477cb-e9df-4609-88b0-3180a2ab8527'	System	27 Apr 2021 04:08:52
User entered 'No (N)'	System	27 Apr 2021 04:08:52

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-04-27T00:08:55-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '9fa477cb-e9df-4609-88b0-3180a2ab8527'	System	27 Apr 2021 04:08:52
User entered '27 Apr 2021 00:08:55'	System	27 Apr 2021 04:08:52

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 16:47:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

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 (73147d23fb84a61c)', Time: '2021-05-04T00:01:32-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fc2fc96a-95c6-48e0-a99f-4f17d1dbc58e'	System	04 May 2021 04:02:55
User entered 'No (N)'	System	04 May 2021 04:02:55

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Have you been exposed to someone with 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 (73147d23fb84a61c)', Time: '2021-05-04T00:01:35-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fc2fc96a-95c6-48e0-a99f-4f17d1dbc58e'	System	04 May 2021 04:02:55
User entered 'No (N)'	System	04 May 2021 04:02:55

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-05-04T00:01:37-04:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: 'fc2fc96a-95c6-48e0-a99f-4f17d1dbc58e'	System	04 May 2021 04:02:55
User entered '04 May 2021 00:01:37'	System	04 May 2021 04:02:55

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 16:47:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 16:47:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 16:47:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 16:47:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 16:47:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 16:47:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:47:18

FDA-CBER-2022-1614-0443383

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 16:47:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 16:47:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 16:47:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:47:18

FDA-CBER-2022-1614-0443401

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 16:47:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 16:47:18

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US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:47:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 16:47:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:47:18

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US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:44:53
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '11 Oct 2022 00:01'	System	19 Nov 2020 16:47:18

US3202085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:53

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:47:18
Amendment Manager: User entered '15 Oct 2022 23:59'	System	19 Nov 2020 16:47:18

US3202085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:44:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-03-05T09:11:43-05:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '98b6aa7e-c349-4508-9f43-1d6ffca04538'	System	05 Mar 2021 14:12:01
User entered 'Yes (Y)'	System	05 Mar 2021 14:12:01

US3202085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:44:53

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-03-05T09:11:55-05:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '98b6aa7e-c349-4508-9f43-1d6ffca04538'	System	05 Mar 2021 14:12:01
User entered 'Yes (Y)'	System	05 Mar 2021 14:12:01

US3202085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:44:53

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:28:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73147d23fb84a61c)', Time: '2021-03-05T09:11:58-05:00', User OID: 'PatientReportedOutcome (US3202085)', ODM File OID: '98b6aa7e-c349-4508-9f43-1d6ffca04538'	System	05 Mar 2021 14:12:01
User entered '05 Mar 2021 09:11:58'	System	05 Mar 2021 14:12:01

US3202085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:39:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 20:48:16

US3202085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	26 Mar 2021 12:39:30
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 20:33:21
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'SCHEDULED' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 20:48:26
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Nov 2020 20:48:16
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:48:16

US3202085
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:39:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 20:48:16

US3202085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:39:30
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:48:16

US3202085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:47:12

US3202085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:44:49
User entered '1'	System	05 Nov 2020 20:47:12

US3202085
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:00:19
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Dec 2020 14:21:54

US3202085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:00:19
User entered '17 Dec 2020'	zackery harmon (b) (4)	30 Dec 2020 14:21:54
	(b) (4)	

US3202085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:00:19
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	30 Dec 2020 14:21:54

US3202085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:00:19
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Dec 2020 14:21:54

US3202085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:04:03
User entered 'Yes (Y)'	zackery harmon (b) (4)	30 Dec 2020 14:21:58
	(b) (4)	

US3202085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User entered '1'	System	30 Dec 2020 14:21:58

US3202085
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:07:11
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	18 Jan 2021 16:29:34
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:07:11
User entered '18 Jan 2021'	Lilian Nukuna (b) (4)	18 Jan 2021 16:29:34

US3202085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:07:11
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4)	18 Jan 2021 16:29:34
	(b) (4)	

US3202085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:07:11
User entered 'left a voice message'	Lilian Nukuna (b) (4) (b) (4)	18 Jan 2021 16:29:34

US3202085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:11:08
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	18 Jan 2021 16:29:46

US3202085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User entered '1'	System	18 Jan 2021 16:29:46

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:14:25
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	22 Feb 2021 17:39:13

US3202085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:14:25
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 11:07:50
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'pd noted oow' (Site from System).	zackery harmon (b) (4) (b) (4)	22 Feb 2021 17:39:22
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Feb 2021 17:39:13
User entered '22 Feb 2021'	zackery harmon (b) (4) (b) (4)	22 Feb 2021 17:39:13

US3202085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:52:06
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:14:25
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	22 Feb 2021 17:39:13

US3202085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:14:25
User entered empty.	zackery harmon (b) (4) (b) (4)	22 Feb 2021 17:39:13

US3202085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:14:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 21:53:02

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:33:55
User entered '1'	System	26 Feb 2021 21:53:02

US3202085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Apr 2021 18:38:13

US3202085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:38:13

US3202085
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Apr 2021 18:38:25

US3202085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
User entered '16 Apr 2021'	zackery harmon (b) (4) (b) (4)	16 Apr 2021 18:38:25

US3202085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	16 Apr 2021 18:38:25

US3202085
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
User entered empty.	zackery harmon (b) (4) (b) (4)	16 Apr 2021 18:38:25

US3202085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	16 Apr 2021 18:38:35

US3202085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:38:35

US3202085

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

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User closed query 'please complete entry' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 13:44:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:21:19
Query 'please complete entry' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 15:18:20
User opened query 'please complete entry' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 20:11:33
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:15:40
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:10:25

US3202085

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

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:21:19
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:15:40
User entered '11 Mar 2021'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:10:25

US3202085

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

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

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 18:51:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:21:19
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:15:40
User entered 'Clinic (Clinic)'	Lilian Nukuna (b) (4)	19 Mar 2021 17:10:25

US3202085

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

Form: Visit Date

Generated On: 09 Jun 2021 15:44:53

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'UNBLND_DECIDE'	System	19 Mar 2021 17:10:25

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:22:04
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 15:18:44
User entered '08 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:18:44
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:17:50
User entered '11 Mar 2021'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:04

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

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 18:51:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:22:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:17:50
User entered '0'	Lilian Nukuna (b) (4)	19 Mar 2021 17:11:04

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:22:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:17:50
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	19 Mar 2021 17:11:04

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	28 Apr 2021 07:01:29
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)	22 Apr 2021 18:36:38
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 'done' (Site from DM).	Teresa Deese (b) (4)	22 Apr 2021 15:25:13
DataPoint Un-verified.	Teresa Deese (b) (4)	22 Apr 2021 15:24:49
Signature has been broken.	Teresa Deese (b) (4)	22 Apr 2021 15:24:49
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Teresa Deese (b) (4)	22 Apr 2021 15:24:49
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)	22 Apr 2021 08:29:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:22:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:17:50
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:04

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User closed query 'Per CDM: Per IRT, subject was unblinded on 08MAR2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 08:54:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:22:04
Query 'Per CDM: Per IRT, subject was unblinded on 08MAR2021. Please review and reconcile.' answered with 'done' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 15:19:08
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	09 Apr 2021 15:18:44
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered by data change (Site from System).	System	09 Apr 2021 15:18:44
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	09 Apr 2021 15:18:32
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 15:18:32
User entered '08 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:18:32
User opened query 'Per CDM: Per IRT, subject was unblinded on 08MAR2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:30:59
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:17:50
User entered '11 Mar 2021'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:04

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:22:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:17:50
User entered 'Placebo (Placebo)'	Lilian Nukuna (b) (4)	19 Mar 2021 17:11:04
	(b) (4)	

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:22:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:17:50
User entered 'Placebo (Placebo)'	Lilian Nukuna (b) (4)	19 Mar 2021 17:11:04
	(b) (4)	

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:22:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:17:50
User entered 'Placebo (Placebo)'	Lilian Nukuna (b) (4)	19 Mar 2021 17:11:04

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:22:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:17:50
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:04

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered '1'	System	19 Mar 2021 17:11:04

US3202085

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

Form: Unblinding

Generated On: 09 Jun 2021 15:44:53

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered '1'	System	19 Mar 2021 17:11:04

US3202085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered empty.	System	31 Mar 2021 18:07:48
DataPoint set to visible.	System	19 Mar 2021 17:11:04

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:44:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered empty.	System	31 Mar 2021 18:07:48
DataPoint set to visible.	System	19 Mar 2021 17:11:04

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '11 Mar 2021'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '15:15'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered '11 Mar 2021 15:15'	System	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '36.8' C	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '98'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'bpm'	System	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '14'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'breaths/min'	System	31 Mar 2021 18:07:48

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '149'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'mmHg'	System	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '96'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'mmHg'	System	31 Mar 2021 18:07:48

US3202085
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:44:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered empty.	System	31 Mar 2021 18:07:48
DataPoint set to visible.	System	19 Mar 2021 17:11:04

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '11 Mar 2021'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '16:27'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered '11 Mar 2021 16:27'	System	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '37.0' C	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '85'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'bpm'	System	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '16'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'breaths/min'	System	31 Mar 2021 18:07:48

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '159'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

FDA-CBER-2022-1614-0443596

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'mmHg'	System	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '96'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:48

US3202085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'mmHg'	System	31 Mar 2021 18:07:48

Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:44:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:58

US3202085

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:07:58

US3202085

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

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:08:15

Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:08:15

US3202085

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

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:08:15

US3202085

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

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'mRNA-1273'	System	31 Mar 2021 18:08:15
DataPoint set to visible.	System	19 Mar 2021 17:11:04

US3202085

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

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '11 Mar 2021'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:08:15

US3202085

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

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '15:55'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:08:15

US3202085

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

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered '11 Mar 2021 15:55'	System	31 Mar 2021 18:08:15

US3202085

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

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Left Arm (LEFT ARM)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:08:15

US3202085

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

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'ONCE'	System	31 Mar 2021 18:08:15

US3202085

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

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered 'INTRAMUSCULAR'	System	31 Mar 2021 18:08:15

US3202085

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:17:44

US3202085

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:17:44

US3202085

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:17:44

US3202085

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered empty.	System	31 Mar 2021 18:17:44

US3202085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:53

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:17:48

US3202085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:53

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:17:48

US3202085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:53

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	zackery harmon (b) (4) (b) (4)	31 Mar 2021 18:17:48

US3202085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:53

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered empty.	System	31 Mar 2021 18:17:48

US3202085

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

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:18

US3202085

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

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:15
User entered '1'	System	19 Mar 2021 17:11:18

US3202085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:31

US3202085
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
User entered '19 Mar 2021'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:31

US3202085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:53

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:31

US3202085
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:44:53
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:31

US3202085
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:52:06
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Mar 2021 17:11:38

US3202085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:28
User entered '1'	System	19 Mar 2021 17:11:38

US3202085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:15:28
User entered '1'	System	19 Mar 2021 17:11:38
DataPoint set to visible.	System	19 Mar 2021 17:11:38

US3202085
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'Yes (Y)'	Teresa Deese (b) (4)	09 Apr 2021 18:30:26

US3202085
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '9 Apr 2021'	Teresa Deese (b) (4)	09 Apr 2021 18:30:26

US3202085
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	09 Apr 2021 18:30:26

US3202085
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:44:53
Folder OID

Audit	User	Time (GMT)
User entered 'OLD29'	System	09 Apr 2021 18:30:26

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'Yes (Y)'	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '9 Apr 2021'	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '13:11'	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '9 Apr 2021 13:11'	System	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '36.7' C	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered empty.	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '84'	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 18:08:40
User entered '18'	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:44:53
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '145'	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '90'	Teresa Deese (b) (4)	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:31:30

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:44:53
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'Yes (Y)'	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '9 Apr 2021'	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '14:30'	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '9 Apr 2021 14:30'	System	09 Apr 2021 18:31:59

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '36.7' C	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:44:53
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered empty.	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 18:08:40
User entered '82'	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 18:31:59

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:44:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '14'	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 18:31:59

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '149'	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:31:59

US3202085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '98'	Teresa Deese (b) (4)	09 Apr 2021 18:31:59

US3202085
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:44:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 18:31:59

US3202085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:53

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'No (N)'	Teresa Deese (b) (4)	09 Apr 2021 18:30:54

US3202085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:53

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered empty.	Teresa Deese (b) (4)	09 Apr 2021 18:30:54

US3202085
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

Was study treatment given?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'Yes (Y)'	Teresa Deese (b) (4)	09 Apr 2021 18:30:50

US3202085
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53
If No, reason not given

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered empty.	Teresa Deese (b) (4)	09 Apr 2021 18:30:50

US3202085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered empty.	Teresa Deese (b) (4)	09 Apr 2021 18:30:50

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	09 Apr 2021 18:30:50
DataPoint set to visible.	System	19 Mar 2021 17:11:38

US3202085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '9 Apr 2021'	Teresa Deese (b) (4)	09 Apr 2021 18:30:50

US3202085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '13:54'	Teresa Deese (b) (4)	09 Apr 2021 18:30:50

Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '9 Apr 2021 13:54'	System	09 Apr 2021 18:30:50

US3202085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'Left Arm (LEFT ARM)'	Teresa Deese (b) (4)	09 Apr 2021 18:30:50

US3202085
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:44:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Apr 2021 18:30:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Apr 2021 18:30:50

US3202085
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:44:53

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered 'Yes (Y)'	Teresa Deese (b) (4)	09 Apr 2021 18:30:31

US3202085

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:53

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:30:31

US3202085
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:44:53

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:17
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:05:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	30 Oct 2020 15:41:09
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:10:02

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 15:44:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 15:44:55
Data point term sent to Coder	System	30 Oct 2020 15:44:06
User entered 'Post traumatic stress disorder'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'No (N)'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'No (N)'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'No (N)'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '15 Oct 2020'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Yes (Y)'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'No (N)'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:43:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 15:43:21
User entered 'None (NONE)' reason for change: Data Entry Error	Teresa Deese (b) (4)	30 Oct 2020 15:43:21
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 15:43:09
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53
None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User closed query 'Per CDM: Other action taken is 'NONE' however, there is a corresponding Concomitant Medication record (#4) for 'POST TRAUMATIC STRESS DISORDER'? Please review and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:03:48
Query 'Per CDM: Other action taken is 'NONE' however, there is a corresponding Concomitant Medication record (#4) for 'POST TRAUMATIC STRESS DISORDER'? Please review and reconcile accordingly.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	21 Nov 2020 17:25:24
User entered '0' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	21 Nov 2020 17:25:20
User opened query 'Per CDM: Other action taken is 'NONE' however, there is a corresponding Concomitant Medication record (#4) for 'POST TRAUMATIC STRESS DISORDER'? Please review and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:21:08
User entered '1'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '1' reason for change: Data Entry Error	zackery harmon (b) (4)	21 Nov 2020 17:25:20
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Unknown (UNKNOWN)'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'subject to let us know new Rx name-unable to recall at vs today'	Teresa Deese (b) (4)	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 15:43:09

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

AEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:20:55
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'USA-US128-2021-mRNA-1273-P301000010'	System	22 Feb 2021 19:53:08
User entered 'New'	(b) (4), (b) (6)	22 Feb 2021 19:53:08

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis, LLT: Pancreatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 19:15:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 19:15:01
Data point term sent to Coder	System	22 Feb 2021 19:14:34
User entered 'PANCREATITIS'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'No (N)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'No (N)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'No (N)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User closed query 'PV Query: Event end date for pancreatitis was reported as 16 Feb 2021. However, the hospitalization discharge date was reported as 09 Feb 2021. Please consider updating event end date. If not updating, please clarify.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:46:11
Query 'PV Query: Event end date for pancreatitis was reported as 16 Feb 2021. However, the hospitalization discharge date was reported as 09 Feb 2021. Please consider updating event end date. If not updating, please clarify.' answered with 'CORRECTED' (Site from Safety).	Erica Osmundsen (b) (4)	09 Apr 2021 17:39:04
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 17:38:58
User entered '09 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:38:58
User opened query 'PV Query: Event end date for pancreatitis was reported as 16 Feb 2021. However, the hospitalization discharge date was reported as 09 Feb 2021. Please consider updating event end date. If not updating, please clarify.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:44:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
Signature has been broken.	Teresa Deese (b) (4)	01 Apr 2021 16:12:34
User entered '16 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Apr 2021 16:12:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'PV Query: Event end date for pancreatitis was reported as 16 Feb 2021. However, the hospitalization discharge date was reported as 09 Feb 2021. Please consider updating event end date. If not updating, please clarify.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 16:04:44

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'PV Query: Event end date for pancreatitis was reported as 16 Feb 2021. However, the hospitalization discharge date was reported as 09 Feb 2021. Please consider updating event end date. If not updating, please clarify.' answered with 'CORRECTED ENTRY ERROR' (Site from Safety). DataPoint Un-verified.	Erica Osmundsen (b) (4)	05 Mar 2021 22:07:42
	Erica Osmundsen (b) (4)	05 Mar 2021 22:07:31
User entered '09 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 22:07:31
User opened query 'PV Query: Event end date for pancreatitis was reported as 16 Feb 2021. However, the hospitalization discharge date was reported as 09 Feb 2021. Please consider updating event end date. If not updating, please clarify.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:58:16
	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '16 Feb 2021'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
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)	10 Mar 2021 16:06:15
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 test was negative at hospital' (Site from Safety).	Erica Osmundsen (b) (4)	05 Mar 2021 22:07:57
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:01:52
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '1'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:55:47
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	26 Feb 2021 23:01:26
User entered '09 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	26 Feb 2021 23:01:26
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '16 Feb 2021'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:55:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	26 Feb 2021 23:01:06
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	26 Feb 2021 23:01:06
DataPoint Un-verified.	Erica Osmundsen (b) (4)	26 Feb 2021 23:01:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	26 Feb 2021 23:01:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	22 Feb 2021 19:14:01
User entered 'Unknown (UNK)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '13' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:41:17
User closed query 'per Hospital records moved to medical floor 30Jan2021, Please verify.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:08:04
Query 'per Hospital records moved to medical floor 30Jan2021, Please verify.' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	01 Apr 2021 16:07:30
Signature has been broken.	Teresa Deese (b) (4)	01 Apr 2021 16:07:20
User entered '15' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Apr 2021 16:07:20
User opened query 'per Hospital records moved to medical floor 30Jan2021, Please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:20:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 17:19:56
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:19:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '19' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 22:07:31
DataPoint Un-verified.	Erica Osmundsen (b) (4)	26 Feb 2021 23:01:06
User entered '13' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	26 Feb 2021 23:01:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

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Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:19:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'Per CDM: Response noted - please update CM/CP when data is available. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:10:10
Query 'Per CDM: Response noted - please update CM/CP when data is available. Thank you' answered by data change (Site from DM).	System	05 Mar 2021 22:07:31
DataPoint Un-verified.	Erica Osmundsen (b) (4)	05 Mar 2021 22:07:31
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 22:07:31
User opened query 'Per CDM: Response noted - please update CM/CP when data is available. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:39:27
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:39:27
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'waiting on records' (Site from DM).	zackery harmon (b) (4) (b) (4)	01 Mar 2021 21:31:20

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:57:59
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '1'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'Per CDM: Please verify that Concomitant Medication is checked. However no corresponding Con medication is provided. Please review and update accordingly. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 07:47:25
Query 'Per CDM: Please verify that Concomitant Medication is checked. However no corresponding Con medication is provided. Please review and update accordingly. Else clarify. ' answered with 'Rx list updated' (Site from DM).	Teresa Deese (b) (4)	17 Mar 2021 16:38:21
User opened query 'Per CDM: Please verify that Concomitant Medication is checked. However no corresponding Con medication is provided. Please review and update accordingly. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:12:21
DataPoint Un-verified.	Erica Osmundsen (b) (4)	05 Mar 2021 22:07:31
User entered '1' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 22:07:31
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

FDA-CBER-2022-1614-0443744

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User closed query 'per hospital records subject received apheresis as treatment, please verify' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:10:05
Query 'per hospital records subject received apheresis as treatment, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	01 Apr 2021 16:08:43
Signature has been broken.	Teresa Deese (b) (4)	01 Apr 2021 16:07:50
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Apr 2021 16:07:50
User opened query 'per hospital records subject received apheresis as treatment, please verify' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:59:32
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 19:59:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered '0'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered empty.	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:23:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User closed query 'Please complete narrative with details' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:10:29
Query 'Please complete narrative with details' answered with 'additional detail added to narrative, updated list of AEs, Con Meds, Con Procedures and d/c summary redacted and provided as well' (Site from CRA).	Erica Osmundsen (b) (4)	01 Apr 2021 21:05:32
DataPoint Un-verified.	Erica Osmundsen (b) (4)	01 Apr 2021 21:03:51
Signature has been broken.	Erica Osmundsen (b) (4)	01 Apr 2021 21:03:51
User entered 'RECORDS REQUESTED FROM HOSPITALIZATION. SITE MADE AWARE OF THIS SAE ON 22FEB2021. MEDICAL RECORDS HAVE BEEN RECEIVED AND DISCHARGE SUMMARY PROVIDED TO SAFETY REPORTING TEAM. SUBJECT ADMITTED FOR PANCREATITIS, BUT DEVELOPED NUMEROUS OTHER CONDITIONS (ALSO ADDED AS AEs AND SAEs) as learned when records were received.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	01 Apr 2021 21:03:51
User opened query 'Please complete narrative with details' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:21:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:11:38

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:11:32
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:11:30
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:38:54
Query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:38:42
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:38:30
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:18:58

US3202085
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:18:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:00:38
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:39
User entered 'RECORDS REQUESTED FROM HOSPITALIZATION. SITE MADE AWARE OF THIS SAE ON 22FEB2021'	Erica Osmundsen (b) (4)	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 23:01:06
User entered '0'	System	22 Feb 2021 19:14:01

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

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AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:00:56
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:26:26
User entered 'USA-US128-2021-mRNA-1273-P301000010'	(b) (4), (b) (6)	01 Mar 2021 15:26:22

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:00:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Diabetic complications, HLT: Diabetic complications NEC, PT: Diabetic ketoacidosis, LLT: Diabetic ketoacidosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 23:01:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 23:01:56
Data point term sent to Coder	System	26 Feb 2021 23:01:37
User entered 'DIABETIC KETOACIDOSIS'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:00:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

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Folder: Adverse Events

Form: Adverse Events (3)

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Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

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Folder: Adverse Events
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Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	26 Feb 2021 23:02:10
User entered '17 Jan 2021'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:11
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

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AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 23:00:39

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:24:26
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:54
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '09 Feb 2021'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:21
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 23:00:39

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:01:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	26 Feb 2021 23:01:57
User entered '17 Jan 2021'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '09 Feb 2021'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
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Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:24:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 14:40:59
User entered '13' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:40:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '19' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 22:08:23
User entered '13'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

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Folder: Adverse Events

Form: Adverse Events (3)

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

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Folder: Adverse Events

Form: Adverse Events (3)

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

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Folder: Adverse Events

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Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:54
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

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Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:02:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'Per CDM: Please verify that Concomitant Medication check box is checked however there's no corresponding concomitant medication recorded for this AE during this time frame. Please review and update accordingly. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 07:51:11
Query 'Per CDM: Please verify that Concomitant Medication check box is checked however there's no corresponding concomitant medication recorded for this AE during this time frame. Please review and update accordingly. Else clarify. ' answered with 'Rx updated' (Site from DM).	Teresa Deese (b) (4)	17 Mar 2021 16:39:03
User opened query 'Per CDM: Please verify that Concomitant Medication check box is checked however there's no corresponding concomitant medication recorded for this AE during this time frame. Please review and update accordingly. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:58:41
User entered '1'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:14
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:24:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:12:29
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:12:27
User closed query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:12:25
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:39:14
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:39:11

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:39:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:23:04
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:22:23
Query '(REQUERY) PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:21:51
User opened query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:20:59
User opened query '(REQUERY) PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:20:16

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3202085
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
User entered 'RECORDS RECEIVED TODAY FROM HOSPITALIZATION AS REQUESTED WHEN SUBJECT REPORTED PANCREATITIS. THE RECORDS REVEALED ADDITIONAL DIAGNOSES RELATED TO THE HOSPITALIZATION'	Erica Osmundsen (b) (4)	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 23:00:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 23:00:39

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:44
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:26:56
User entered 'USA-US128-2021-mRNA-1273-P301000010'	(b) (4), (b) (6)	01 Mar 2021 15:26:53

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 23:04:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 23:04:55
Data point term sent to Coder	System	26 Feb 2021 23:04:40
User entered 'SEPSIS'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:03:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '09 Feb 2021'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:02
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 23:03:48

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

FDA-CBER-2022-1614-0443809

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '09 Feb 2021'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:24:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 14:40:39
User entered '13' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:40:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '19' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 22:08:45
User entered '13'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'Per CDM: Please verify that Concomitant Medication check box is checked however there's no corresponding concomitant medication recorded for this AE during this time frame. Please review and update accordingly. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:45:57
Query 'Per CDM: Please verify that Concomitant Medication check box is checked however there's no corresponding concomitant medication recorded for this AE during this time frame. Please review and update accordingly. Else clarify. ' answered with 'medication updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	13 Mar 2021 14:14:18
User opened query 'Per CDM: Please verify that Concomitant Medication check box is checked however there's no corresponding concomitant medication recorded for this AE during this time frame. Please review and update accordingly. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:21:43
User entered '1'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:04:44
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:24:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:13:06
User closed query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:13:03
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:13:00
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:41:02
Query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:40:58

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'covid neg. done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:40:55
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:24:59
User opened query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:24:36
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:23:49
User entered 'OCCURRED WITH THE PANCREATITIS AND DKA SAEs as learned per hospital records received'	Erica Osmundsen (b) (4)	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 23:03:48

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:02
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:16:19
User entered 'USA-US128-2021-mRNA-1273-P301000010'	(b) (4), (b) (6)	08 Mar 2021 18:00:40

Adverse event

Audit	User	Time (GMT)
User closed query 'Per MM:Please confirm if this is a sign/symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 08:32:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:50
Query 'Per MM:Please confirm if this is a sign/symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' answered with 'NOT A SYMPTOM OF COVID-19. SUBJECT HAD MULTIPLE NEGATIVE COVID-19 PCR TESTS THROUGHOUT AE PERIOD' (Site from DM).	Erica Osmundsen (b) (4)	12 Apr 2021 14:53:47
User opened query 'Per MM:Please confirm if this is a sign/symptom of covid and if the patient was evaluated for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:54:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:04:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:04:58
Data point term sent to Coder	System	05 Mar 2021 22:03:53

Adverse event

Audit	User	Time (GMT)
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '30 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:22
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '9 Feb 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:05:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 12:57:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '13' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 22:05:00
User entered '18'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:06:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:06:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:06:03
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:06:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:06:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:28:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:30
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 15:56:30
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Mar 2021 15:54:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User closed query 'source AE log = medication also, please verify' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:11:58
Query 'source AE log = medication also, please verify' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	01 Apr 2021 16:10:20
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Apr 2021 16:09:53
User opened query 'source AE log = medication also, please verify' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 20:06:57
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 10:56:21
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	22 Mar 2021 15:55:33
Signature has been broken.	Teresa Deese (b) (4)	22 Mar 2021 15:54:49
User entered '0' reason for change: Data Entry Error	Teresa Deese (b) (4)	22 Mar 2021 15:54:49
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:31:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 08:32:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'added intubation and mechanical ventilation' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 12:20:22
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 08:59:19
User closed query 'Per CDM: Please verify that Concomitant Procedure is checked however corresponding Conmed procedure provided. Please review and update according. Provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:07:43
Query 'Per CDM: Please verify that Concomitant Procedure is checked however corresponding Conmed procedure provided. Please review and update according. Provide clarification. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	01 Apr 2021 16:10:28
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:01
User opened query 'Per CDM: Please verify that Concomitant Procedure is checked however corresponding Conmed procedure provided. Please review and update according. Provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:00:30
Signature has been broken.	Teresa Deese (b) (4)	22 Mar 2021 15:56:30

Concomitant Procedure

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	22 Mar 2021 15:56:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

FDA-CBER-2022-1614-0443860

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Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

US3202085
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:39
User closed query 'PV Query: Please provide results of microbiology test performed on 01/27 as mentioned in DS.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:45:53
User closed query 'PV Query: Please assess if hypertriglyceridemia reported on 01/15 meets criteria for SAE/AE reporting.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:45:49
User closed query 'PV Query: Please advise is CKD and diabetes type 2 for treatment med indications, history of heavy alcohol use and Graves' disease should be considered medical history. If so, please report them as such with appropriate onset / end date.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:45:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
Query 'PV Query: Please provide results of microbiology test performed on 01/27 as mentioned in DS.' answered with 'added information on microbiology tests' (Site from Safety).	Erica Osmundsen (b) (4)	09 Apr 2021 14:20:33
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 14:20:21
User entered 'OCCURRED DURING HOSPITALIZATION FOR PANCREATITIS, SEPSIS, ETC. MICROBIOLOGY TESTS ALL NEGATIVE. FINAL NOTE FROM INFECTIOUS DISEASE SPECIALIST CONSULTATIONS STATE, "fever/WBC possibly all sec to resolving severe pancreatitis" and results note that f/u bcx, SARS-CoV-2, C-diff were negative. Sputum and Ascites microbiology lab notes state "no growth to date" for cultures' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:20:21
Query 'PV Query: Please assess if hypertriglyceridemia reported on 01/15 meets criteria for SAE/AE reporting.' answered with 'determined by PI as not SAE--led to SAE of pancreatitis' (Site from Safety).	Erica Osmundsen (b) (4)	09 Apr 2021 12:25:10

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please advise is CKD and diabetes type 2 for treatment med indications, history of heavy alcohol use and Graves' disease should be considered medical history. If so, please report them as such with appropriate onset / end date.' answered with 'subject reported hyperthyroidism as medical history, no prior history of CKD or diabetes' (Site from Safety).	Erica Osmundsen (b) (4)	09 Apr 2021 12:21:54
User opened query 'PV Query: Please provide results of microbiology test performed on 01/27 as mentioned in DS.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:32:55
User opened query 'PV Query: Please assess if hypertriglyceridemia reported on 01/15 meets criteria for SAE/AE reporting.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:32:41
User opened query 'PV Query: Please advise is CKD and diabetes type 2 for treatment med indications, history of heavy alcohol use and Graves' disease should be considered medical history. If so, please report them as such with appropriate onset / end date.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:32:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:14:00
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:13:58
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:13:55

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Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:41:23
Query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:41:20
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Rx updated' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:41:17
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:26:14
User opened query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:26:01
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:25:32

Narrative

Audit	User	Time (GMT)
User entered 'OCCURRED DURING HOSPITALIZATION FOR PANCREATITIS, SEPSIS, ETC.'	Erica Osmundsen (b) (4)	05 Mar 2021 22:03:45

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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:03:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:03:45

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:53

AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 14:15:33
User entered 'USA-US128-2021-mRNA-1273-P301000010'	(b) (4), (b) (6)	08 Mar 2021 18:01:21

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Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure, unspecified - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:48:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:48:59
Data point term sent to Coder	System	05 Mar 2021 22:28:53
User entered 'ACUTE RENAL FAILURE UNSPECIFIED'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:42
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Form: Adverse Events (6)

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Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events

Form: Adverse Events (6)

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Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events

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AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:28:39

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Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Generated On: 09 Jun 2021 15:44:53
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 14:39:54
User entered '26 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:39:54
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 14:39:34
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 14:39:34
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 14:39:34
User entered '26 Jun 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:39:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '01 Feb 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:07:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:28:39

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Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:00
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events

Form: Adverse Events (6)

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Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Form: Adverse Events (6)

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Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events
Form: Adverse Events (6)
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Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:10
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events

Form: Adverse Events (6)

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Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '09 Feb 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events

Form: Adverse Events (6)

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Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 14:40:08
User entered '13' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:40:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '19'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:37
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:39
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:18
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:44:53
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Form: Adverse Events (6)

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Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:53

Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:54
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:08:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:15:56
User closed query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:15:54
User closed query ' PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:15:50
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:41:45
Query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:41:41

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Narrative

Audit	User	Time (GMT)
Query ' PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Rx updated' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:41:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:29:26
User opened query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:29:03
User opened query ' PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:28:30
User entered 'TEMPORARY DIALYSIS DURING HOSPITALIZATION'	Erica Osmundsen (b) (4)	05 Mar 2021 22:28:39

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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:28:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:28:39

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Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:28:39

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Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:31:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:31:09
Data point term sent to Coder	System	05 Mar 2021 22:30:53
User entered 'TYPE 2 DIABETES MELLITUS'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:27
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:28
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:33
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:10:53
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

FDA-CBER-2022-1614-0443931

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:29:48
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:24
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:11:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:12:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:30:12

US3202085

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 22:30:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:30:12

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:18:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Non-mechanical ileus, PT: Ileus paralytic, LLT: Adynamic ileus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:31:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:31:58
Data point term sent to Coder	System	05 Mar 2021 22:31:54
User entered 'ADYNAMIC ILEUS'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:18:56
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:18:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:18:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
User entered empty.	System	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '09 Feb 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
User entered empty.	System	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:35
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:36
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:19:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:31:33

US3202085

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
User entered '0'	System	05 Mar 2021 22:31:33

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18
User entered '1'	System	05 Mar 2021 22:31:33

FDA-CBER-2022-1614-0443975

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:18

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:37:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:37:58
Data point term sent to Coder	System	05 Mar 2021 22:37:55
User entered 'CONSTIPATION'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:26
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
User entered empty.	System	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:34
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '29 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

FDA-CBER-2022-1614-0443987

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
User entered empty.	System	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:40
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:52
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:54
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:20:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085
Folder: Adverse Events
Form: Adverse Events (9)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:37:33

US3202085

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
User entered '0'	System	05 Mar 2021 22:37:33

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26
User entered '1'	System	05 Mar 2021 22:37:33

FDA-CBER-2022-1614-0444011

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:26

FDA-CBER-2022-1614-0444012

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer, LLT: Gastric ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 23:04:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 23:04:05
Data point term sent to Coder	System	05 Mar 2021 22:40:57
User entered 'GASTRIC ULCER WITHOUT HEMORRHAGE OR PERFORATION'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

FDA-CBER-2022-1614-0444013

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:21:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:30:27
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:08:49
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'this will be unknown unless subj has another EGD in future' (Site from DM).	Teresa Deese (b) (4)	01 Apr 2021 16:13:37
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:32:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:30:41
User closed query 'source = end date 05Mar2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:30:37
Query 'source = end date 05Mar2021, please verify' answered with 'that is the date coordinator changed date resolved to ongoing- not end date of AE' (Site from CRA).	Teresa Deese (b) (4)	01 Apr 2021 16:14:50
User opened query 'source = end date 05Mar2021, please verify' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 20:25:27
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:24:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Mar 2021 22:40:58
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	05 Mar 2021 22:40:58
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Mar 2021 22:40:42
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:25:09
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 20:25:07
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:24:53
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:21
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:24
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

FDA-CBER-2022-1614-0444033

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

FDA-CBER-2022-1614-0444037

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:22:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:24:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:24:45
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085
Folder: Adverse Events
Form: Adverse Events (10)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:24:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 22:40:42

US3202085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:40:42

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:25:50
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:40:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:40:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
Data point term sent to Coder	System	05 Mar 2021 22:41:57
User entered 'UNSPECIFIED GASTRITIS WITHOUT BLEEDING'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:25:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:25:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:25:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:25:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:25:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
User entered empty.	System	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '9 Feb 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
User entered empty.	System	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:14
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:17
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:33
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:28:06
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 20:28:05
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:26:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085
Folder: Adverse Events
Form: Adverse Events (11)
Generated On: 09 Jun 2021 15:44:53
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:28:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:28:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:28:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:28:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
User entered '0'	System	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46
User entered '1'	System	05 Mar 2021 22:41:55

US3202085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:46

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:32:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol withdrawal syndrome, LLT: Alcohol withdrawal syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:48:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:48:59
Data point term sent to Coder	System	05 Mar 2021 22:43:59
User entered 'ALCOHOL WITHDRAWAL'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:32:40
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:32:42
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

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US3202085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:32:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:32:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:32:49
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
User entered empty.	System	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:32:51
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:32:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '09 Feb 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:32:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
User entered empty.	System	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:07
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:19
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

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US3202085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:21
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

FDA-CBER-2022-1614-0444103

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:36
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085
Folder: Adverse Events
Form: Adverse Events (12)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:33:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:42:59

US3202085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
User entered '0'	System	05 Mar 2021 22:42:59

US3202085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55
User entered '1'	System	05 Mar 2021 22:42:59

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:55

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicidal ideation, LLT: Suicidal ideation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:35:54
User coded data point as Term Coded data point by User:　　(b) (6)　　 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:35:54
Data point term sent to Coder	System	05 Mar 2021 22:43:59
User entered 'SUICIDAL IDEATIONS'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
User entered empty.	System	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:28
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '22 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
User entered empty.	System	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:42
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:52
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:57
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:34:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

FDA-CBER-2022-1614-0444148

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

US3202085
Folder: Adverse Events
Form: Adverse Events (13)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:35:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:43:50

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
User entered '0'	System	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02
User entered '1'	System	05 Mar 2021 22:43:50

US3202085

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:02

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 14:14:39
User entered 'USA-US128-2021-mRNA-1273-P301000010'	(b) (4), (b) (6)	08 Mar 2021 18:02:17

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm if this pneumonia is COVID related ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 08:29:51
Query 'Per MM, please confirm if this pneumonia is COVID related ' answered with 'CONFIRMED NOT COVID-19 RELATED' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 14:23:27
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:31:30
User opened query 'Per MM, please confirm if this pneumonia is COVID related ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:15:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:48:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:48:58
Data point term sent to Coder	System	05 Mar 2021 22:48:00
User entered 'PNEUMONIA'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:27
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:31:30
User closed query 'AE source log= 05Feb2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:31:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
Query 'AE source log= 05Feb2021, Please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 14:23:34
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 14:23:15
User entered '05 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:23:15
User opened query 'AE source log= 05Feb2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:29:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '27 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:29:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '09 Feb 2021'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:31:36
User closed query 'Per notes moved to medical floor 30Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:31:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
Query 'Per notes moved to medical floor 30Jan2021, please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 14:30:00
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 14:24:44
User entered '13' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:24:44
User opened query 'Per notes moved to medical floor 30Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:30:37
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:11
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '19'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:30:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:31:41
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 08:31:41
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'medications were entered but had pneumonia entered with additional indications as well. indication listings reformatted for clarity on the ConMed page' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 14:35:31
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:35:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '1'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:31:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered '0'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:31:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:31:05
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:04:07
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:31:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	19 Mar 2021 13:04:07
User closed query ' PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:14:55
User closed query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:14:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:14:48
Query ' PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:42:12
Query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'done' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:42:08

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Rx updated' (Site from Safety).	Teresa Deese (b) (4)	17 Mar 2021 16:42:03
User opened query ' PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:27:43
User opened query 'PV Query: Please confirm if the subject had any prior medical history relevant to the events. If so, please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:27:27
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:27:13
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Mar 2021 22:48:13
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Mar 2021 22:48:13
User entered 'SUBJECT ADMITTED FOR PANCREATITIS AND FOUND TO HAVE PNEUMONIA-SAME HOSPITALIZATION AS OTHER SAES' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 22:48:13
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (14)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
User entered empty.	Erica Osmundsen (b) (4)	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:47:04

US3202085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 22:47:04

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40

US3202085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Peritoneal and retroperitoneal conditions, HLT: Peritoneal and retroperitoneal disorders, PT: Ascites, LLT: Ascites - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:27:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:27:46
Data point term sent to Coder	System	09 Apr 2021 12:19:04
User entered 'Loculated Ascites'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:08
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

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Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '27 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
User entered empty.	System	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:16
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '04 Feb 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
User entered empty.	System	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:22
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:24
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:26
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:28
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:30
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:33
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:40
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

FDA-CBER-2022-1614-0444216

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:47
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:49
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered '1'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:32:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085
Folder: Adverse Events
Form: Adverse Events (15)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:33:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:00

US3202085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
User entered '0'	System	09 Apr 2021 12:19:00

US3202085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40
User entered '1'	System	09 Apr 2021 12:19:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:17:40

US3202085
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:33:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:52:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:52:30
Data point term sent to Coder	System	09 Apr 2021 14:43:50
User entered 'dyspnea'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:33:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:33:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:33:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:33:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '06 Feb 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:33:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:33:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:33:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:43:14

US3202085
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:44:53

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:44:53
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085
Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:44:53

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

Folder: Adverse Events
Form: Adverse Events (16)
Generated On: 09 Jun 2021 15:44:53
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '1'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:34:59
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 14:43:14

US3202085

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 14:43:14

US3202085
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:44:53
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
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)	09 Apr 2021 15:07:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:07:24
Data point term sent to Coder	System	09 Apr 2021 14:56:23
User entered 'hypertension'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:44:53
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:44:53
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 19:37:35
User entered '27 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:37:35
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 19:37:27
User entered '27 Jun 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:37:27
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 17:58:17
User entered '01 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:58:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '08 Mar 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:35:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:00
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

FDA-CBER-2022-1614-0444282

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

FDA-CBER-2022-1614-0444283

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

FDA-CBER-2022-1614-0444286

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

FDA-CBER-2022-1614-0444288

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '1'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085
Folder: Adverse Events
Form: Adverse Events (17)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:55:27

US3202085

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 14:55:27

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 14:55:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Dysphonia, LLT: Dysphonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:08:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:08:56
Data point term sent to Coder	System	09 Apr 2021 14:57:25
User entered 'dysphonia'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

FDA-CBER-2022-1614-0444301

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '30 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
User entered empty.	System	09 Apr 2021 14:56:35

FDA-CBER-2022-1614-0444304

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 17:39:40
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:39:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 17:39:40
User entered '27 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:39:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:36:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
User entered empty.	System	09 Apr 2021 14:56:35

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:35:26
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '1'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Signature has been broken.	Erica Osmundsen (b) (4)	09 Apr 2021 17:39:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:39:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 15:16:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085
Folder: Adverse Events
Form: Adverse Events (18)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:16:11
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
User entered '0'	System	09 Apr 2021 14:56:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28
User entered '1'	System	09 Apr 2021 14:56:35

US3202085

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:28

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:03:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:03:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
Data point term sent to Coder	System	09 Apr 2021 16:01:34
User entered 'HYPERTRIGLYCERIDEMIA'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

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US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:49
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:03:18
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:38:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Severity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:11:58
User closed query 'source = grade 2/moderate, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:11:43
Query 'source = grade 2/moderate, please verify' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 20:19:05
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:15:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:15:53
User opened query 'source = grade 2/moderate, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:39:36
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 18:39:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:39:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:39:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:39:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:39:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:39:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:39:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:39:53
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:03:18
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:39:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:00
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:03:18
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

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US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:03:18
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered '1'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:40:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:03:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:41:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:03:18
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (19)
Generated On: 09 Jun 2021 15:44:53
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:41:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:03:18
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 16:01:00

US3202085

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:01:00

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Electrolyte imbalance NEC, PT: Electrolyte imbalance, LLT: Electrolyte imbalance - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:19:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:19:44
Data point term sent to Coder	System	09 Apr 2021 19:39:50
User entered 'INTERMITTENT ELECTROLYTE IMBALANCES'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

FDA-CBER-2022-1614-0444371

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 12:59:26
User closed query 'source = 15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 12:59:24
Query 'source = 15Jan2021, please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	19 Apr 2021 18:20:03
Signature has been broken.	Erica Osmundsen (b) (4)	19 Apr 2021 18:19:37
User entered '15 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Apr 2021 18:19:37
User opened query 'source = 15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:36:36
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:18
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '17 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
User entered empty.	System	09 Apr 2021 19:38:54

FDA-CBER-2022-1614-0444374

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '09 Feb 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
User entered empty.	System	09 Apr 2021 19:38:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:48
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

FDA-CBER-2022-1614-0444379

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:50
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

FDA-CBER-2022-1614-0444381

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:36:59
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

FDA-CBER-2022-1614-0444387

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

FDA-CBER-2022-1614-0444393

US3202085

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:17
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '1'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

US3202085
Folder: Adverse Events
Form: Adverse Events (20)
Generated On: 09 Jun 2021 15:44:53
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 19:38:54

FDA-CBER-2022-1614-0444399

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
User entered '0'	System	09 Apr 2021 19:38:54

US3202085

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45
User entered '1'	System	09 Apr 2021 19:38:54

US3202085

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 15:44:53

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:44:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:17
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 12:56:13
User closed query 'source also = TPN for IV nutrition 27Jan-08Feb2021 and KCL infusions 20 meq x 1 23Jan2021 and x3 on 19Jan2021, Please verify.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 12:56:11
Query 'source also = TPN for IV nutrition 27Jan-08Feb2021 and KCL infusions 20 meq x 1 23Jan2021 and x3 on 19Jan2021, Please verify.' answered with 'added TPN, updated ConMed line 27 dosage from 60meq X 1 to 20meq tid and added the dosage on 23jan21 PER QUERY' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 21:14:13
User opened query 'source also = TPN for IV nutrition 27Jan-08Feb2021 and KCL infusions 20 meq x 1 23Jan2021 and x3 on 19Jan2021, Please verify.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:08:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User closed query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 15:32:04
Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' answered with 'check the Rx list' (Site from DM).	Teresa Deese (b) (4)	18 Mar 2021 15:55:15
User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 09:12:19
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:58:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 14:57:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 14:57:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:53
Data point term sent to Coder	System	26 Aug 2020 18:00:09
User entered 'Propranolol'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Migraine'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Apr 2021 19:18:26
Signature has been broken.	Erica Osmundsen (b) (4)	14 Apr 2021 04:24:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '20'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '10 Apr 2019'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:45:53
User closed query 'source=end date 15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:42:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'source=end date 15Jan2021, please verify' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 15:23:48
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:23:42
User opened query 'source=end date 15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 15:58:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 15:56:35
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:46:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:23:42
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 15:56:38
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User entered '1'	System	26 Aug 2020 17:59:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User entered '1'	System	26 Aug 2020 17:59:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:41
User entered '804 (804)'	System	26 Aug 2020 17:59:15

FDA-CBER-2022-1614-0444421

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:53
Data point term sent to Coder	System	26 Aug 2020 18:00:12
User entered 'Topiramate'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'migraine'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '25'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	zackery harmon (b) (4)	26 Aug 2020 17:59:56
	(b) (4)	

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

FDA-CBER-2022-1614-0444429

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jun 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:46:21
User closed query 'source=15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:46:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'source=15Jan2021, please verify' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 15:24:47
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:24:29
User opened query 'source=15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 16:27:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:46:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:24:29
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 16:26:34
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User entered '1'	System	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User entered '1'	System	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:47
User entered '804 (804)'	System	26 Aug 2020 17:59:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:50:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:50:46
Data point term sent to Coder	System	17 Sep 2020 18:49:33
Coding entries removed.	(b) (4), (b) (6)	17 Sep 2020 18:48:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:58:57
Data point term sent to Coder	System	26 Aug 2020 18:01:13
User entered 'Methimazole'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	zackery harmon (b) (4)	26 Aug 2020 18:00:34
	(b) (4)	

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User closed query 'Per DM CLR: Please update the indication to reflect the specific type of THYROID ISSUE. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:14:31
Query 'Per DM CLR: Please update the indication to reflect the specific type of THYROID ISSUE. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'QUERY CORRECTED' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 18:49:04
User entered 'hyperthyroid' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 18:48:39
User opened query 'Per DM CLR: Please update the indication to reflect the specific type of THYROID ISSUE. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 11:23:12
User entered 'thyroid issues'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '5'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '05 Jun 2020'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	26 Aug 2020 18:00:34

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	26 Aug 2020 18:00:34

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	26 Aug 2020 18:00:34

FDA-CBER-2022-1614-0444457

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 21:00:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 21:00:26
Data point term sent to Coder	System	03 Nov 2020 20:59:14
User entered 'Remeron'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'post traumatic stress disorder'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '15'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '15 Oct 2020'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	03 Nov 2020 20:58:31

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	03 Nov 2020 20:58:31

FDA-CBER-2022-1614-0444474

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	03 Nov 2020 20:58:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 22:58:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 22:58:40
Data point term sent to Coder	System	09 Mar 2021 22:58:05
User entered 'ZOSYN'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:47:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 15:59:00
User entered '3/0.375' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:59:00
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '3.375'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'g (g)'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:47:20
User closed query 'q 12 per source MAR, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:47:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'q 12 per source MAR, please verify' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 15:41:03
User entered 'twice daily (BID)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:40:33
User opened query 'q 12 per source MAR, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:44:23
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 15:21:52
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:47:28
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 15:22:58
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:47:33
User closed query 'per MAR dose change on 25Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:47:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '02 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:56:08
Query 'per MAR dose change on 25Jan2021, please verify' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 15:41:10
User entered '25 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:40:25
User opened query 'per MAR dose change on 25Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:50:10
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 15:23:12
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '31 Jan 2021'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User entered '2'	System	09 Apr 2021 15:40:33
User entered '1'	System	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User entered '1'	System	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:14
User entered '804 (804)'	System	09 Mar 2021 22:57:49

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: MUPIROCIN, PRODUCTSYNONYM: BACTROBAN [MUPIROCIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:09:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:09:57
Data point term sent to Coder	System	17 Mar 2021 15:16:21
User entered 'bactroban nasal'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'prophylaxis-(in hospital when intubated)'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '1'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'g (g)'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Nasal (NASAL)'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '22 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User entered '2'	System	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User entered '1'	System	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:43
User entered '804 (804)'	System	17 Mar 2021 15:15:48

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:18:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:18:36
Data point term sent to Coder	System	17 Mar 2021 15:17:22
User entered 'pepcid'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'gastritis'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '20'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:40:45
User closed query 'source = 15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:40:44
Query 'source = 15Jan2021, please verify' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 20:21:53
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:21:39
User entered '15 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:21:39
User opened query 'source = 15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:48:41
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 18:48:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:48:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:50:38
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 15:25:31
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:48:50
User closed query 'Subject discharged on 09Feb2021, please verify end date' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:48:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Subject discharged on 09Feb2021, please verify end date' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 15:50:56
User entered '09 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:50:38
User opened query 'Subject discharged on 09Feb2021, please verify end date' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:51:18
Query 'please verify end date as this is IV.' canceled (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:50:49
User opened query 'please verify end date as this is IV.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 15:25:56
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 15:25:35
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User entered '2'	System	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User entered '1'	System	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:49
User entered '804 (804)'	System	17 Mar 2021 15:16:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:24:43
Data point term sent to Coder	System	17 Mar 2021 15:24:28
User entered 'lactated ringers'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User closed query 'source= 2,000, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:49:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:49:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'source= 2,000, please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 15:51:17
User entered '2000' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:51:12
User opened query 'source= 2,000, please verify' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 19:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 19:23:50
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '1000'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:51:59
Query 'source=mg, please verify' canceled (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:51:40
User opened query 'source=mg, please verify' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 19:24:53
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 19:24:26
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mL (mL)'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User entered empty.	System	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User entered empty.	System	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:54
User entered empty.	System	17 Mar 2021 15:23:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:53:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:53:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	09 Apr 2021 19:39:53
Coding entries removed.	Erica Osmundsen (b) (4)	09 Apr 2021 19:39:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:13:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:13:33
Data point term sent to Coder	System	17 Mar 2021 15:26:28
User entered 'sodium chloride 0.9%'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:49:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 19:39:41
User entered 'INTERMITTENT ELECTROLYTE IMBALANCES' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:39:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '100'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mL (mL)'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User entered empty.	System	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User entered empty.	System	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:32
User entered empty.	System	17 Mar 2021 15:25:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:27:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:27:51
Data point term sent to Coder	System	17 Mar 2021 15:27:29
User entered 'zosyn'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:49:58
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:51:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' answered with 'UPDATED PRE REQUESTED FORMAT BUT NOT HOW THIS DRUG DOSAGE IS GENERALLY NOTED--4 G PIPERACILLIN/ .5 G TAZOBACTAM SODIUM)' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 15:58:29
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 15:57:07
User entered '4/0.5' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:57:07
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 02:35:35
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '4.5'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'g (g)'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:44:53
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User entered '1'	System	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User entered '1'	System	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:44
User entered '804 (804)'	System	17 Mar 2021 15:27:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
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) (b) (4)	17 Mar 2021 20:17:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 20:17:07
Data point term sent to Coder	System	17 Mar 2021 15:28:31
User entered 'albumin human 5%'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '2000'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mL (mL)'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User entered empty.	System	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User entered empty.	System	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:18:56
User entered empty.	System	17 Mar 2021 15:28:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:44:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:44:49
Data point term sent to Coder	System	09 Apr 2021 14:31:30
Coding entries removed.	Erica Osmundsen (b) (4)	09 Apr 2021 14:30:55
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 20:17:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 20:17:08
Data point term sent to Coder	System	17 Mar 2021 15:30:32
User entered 'albuterol HFA'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:50:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:52:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with '2 SEPARATE CONDITIONS THAT ARE BOTH LISTED AS AEs. I reformatted entry for clarity' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 14:31:27
User entered '1.) DYSPNEA 2.) PNEUMONIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:30:55
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:45:25
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 02:36:45
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'DYSPNEA/pneumonia' reason for change: Data Entry Error	Teresa Deese (b) (4)	17 Mar 2021 15:30:08
User entered 'dyspnea'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '90'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:08
Query 'source=mcg , please verify' canceled (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 19:44:06
User opened query 'source=mcg , please verify' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 19:31:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 19:29:44
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'ug (ug)'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'four times daily (QID)'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

FDA-CBER-2022-1614-0444608

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '7 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User entered '4'	System	17 Mar 2021 15:29:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User entered '1'	System	17 Mar 2021 15:29:50

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:23
User entered '804 (804)'	System	17 Mar 2021 15:29:50

FDA-CBER-2022-1614-0444619

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
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: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:25:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:25:33
Data point term sent to Coder	System	17 Mar 2021 15:31:32
User entered 'pantoprazole'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'GASTRIc ulcer' reason for change: Data Entry Error	Teresa Deese (b) (4)	17 Mar 2021 15:31:18
User entered 'gastritis'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '40'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '27 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:44:53
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '8 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User entered '2'	System	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User entered '1'	System	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:19:29
User entered '804 (804)'	System	17 Mar 2021 15:31:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPTOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:29:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:29:34
Data point term sent to Coder	System	17 Mar 2021 15:32:33
User entered 'liptor'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User closed query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that matches with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:53:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that matches with this condition? Kindly verify and update accordingly, else clarify. ' answered with 'UPDATED PER SOURCE' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 16:01:16
User opened query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that matches with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:36:14
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'hypertriglyceridemia'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '40'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '30 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	17 Mar 2021 15:32:07

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
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)	17 Mar 2021 15:33:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:33:43
Data point term sent to Coder	System	17 Mar 2021 15:33:34
User entered 'tylenol'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '650'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User entered empty.	System	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User entered empty.	System	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:12
User entered empty.	System	17 Mar 2021 15:33:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:10:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:10:58
Data point term sent to Coder	System	17 Mar 2021 15:34:34
User entered 'benadryl'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'prophylaxis during dialysis'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '50'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User entered empty.	System	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User entered empty.	System	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:19
User entered empty.	System	17 Mar 2021 15:34:22

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;SODIUM CHLORIDE, PRODUCTSYNONYM: DEXTROSE 5% AND 0.9% NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:27:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:27:55
Data point term sent to Coder	System	17 Mar 2021 15:37:42
User entered 'dextrose 5%/saline .45%'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '125'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'ml/hr'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'continous'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '18 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User entered empty.	System	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User entered empty.	System	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:34
User entered empty.	System	17 Mar 2021 15:37:06

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:19:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:19:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:10:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:10:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	09 Apr 2021 19:40:54
Coding entries removed.	Erica Osmundsen (b) (4)	09 Apr 2021 19:40:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:26:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:26:33
Data point term sent to Coder	System	17 Mar 2021 15:38:44

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
User entered 'magnesium sulfate/water 2000 mg/50 ml'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:51:15
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 19:40:28
User entered 'INTERMITTENT ELECTROLYTE IMBALANCES' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:40:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '50'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mL (mL)'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User entered empty.	System	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User entered empty.	System	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:39
User entered empty.	System	17 Mar 2021 15:38:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE HYDROCHLORIDE, PRODUCTSYNONYM: PRECEDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:23:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:23:56
Data point term sent to Coder	System	12 Apr 2021 13:23:33
Coding entries removed.	Erica Osmundsen (b) (4)	12 Apr 2021 13:22:42
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE HYDROCHLORIDE, PRODUCTSYNONYM: PRECEDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:40:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:40:44
Data point term sent to Coder	System	17 Mar 2021 15:39:44
User entered 'precedex'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:51:28
User closed query 'Per CDM: Please provide the indication to reflect the underlying medical condition that this medication is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:56:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per CDM: Please provide the indication to reflect the underlying medical condition that this medication is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Erica Osmundsen (b) (4)	12 Apr 2021 13:27:26
DataPoint Un-verified.	Erica Osmundsen (b) (4)	12 Apr 2021 13:22:42
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Apr 2021 13:22:42
User opened query 'Per CDM: Please provide the indication to reflect the underlying medical condition that this medication is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:13:50
User closed query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:10:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify.' answered with 'PROCEDURAL MEDICATION ' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 16:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:47:06
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 15:33:35
User opened query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sedation (intubation)'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '100'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mL (mL)'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User entered empty.	System	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User entered empty.	System	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:20:57
User entered empty.	System	17 Mar 2021 15:39:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CHLORDIAZEPOXIDE, PRODUCTSYNONYM: LIBRIUM [CHLORDIAZEPOXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:04:54
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 Apr 2021 08:04:54
Data point term sent to Coder	System	09 Apr 2021 16:11:56
Coding entries removed.	Erica Osmundsen (b) (4)	09 Apr 2021 16:11:20
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CHLORDIAZEPOXIDE, PRODUCTSYNONYM: LIBRIUM [CHLORDIAZEPOXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:29:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:29:34
Data point term sent to Coder	System	17 Mar 2021 15:40:47
User entered 'librium'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:51:48
User closed query 'hospital notes = alcohol withdrawal, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:51:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'hospital notes = alcohol withdrawal, please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 16:11:51
User entered 'ALCOHOL WITHDRAWAL' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 16:11:20
User opened query 'hospital notes = alcohol withdrawal, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 15:58:07
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 15:57:43
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'PTSD'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '10'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'three times daily (TID)'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:51:56
User closed query 'source= 17Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:51:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'source= 17Jan2021, please verify' answered with 'TRANSCRIPTION ERROR UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 17:40:13
User entered '17 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:40:00
User opened query 'source= 17Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 15:51:12
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 15:34:14
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '12 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '25 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User entered '3'	System	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User entered '1'	System	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:16
User entered '804 (804)'	System	17 Mar 2021 15:40:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:42:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:42:43
Data point term sent to Coder	System	17 Mar 2021 15:41:49
User entered 'heparin'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'DVT prophylaxis'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '5000'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'IU (IU)'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:44:53
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:52:07
User closed query 'per hospital MAR = q 8 hours, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:52:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'per hospital MAR = q 8 hours, please verify' answered with 'CORRECTED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 17:41:19
User entered 'three times daily (TID)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:41:11
User opened query 'per hospital MAR = q 8 hours, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 16:08:02
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:07:29
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '18 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '30 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User entered '3'	System	09 Apr 2021 17:41:11
User entered '2'	System	17 Mar 2021 15:41:38

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User entered '1'	System	17 Mar 2021 15:41:38

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:22
User entered '804 (804)'	System	17 Mar 2021 15:41:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:44:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:44:55
Data point term sent to Coder	System	17 Mar 2021 15:43:55
User entered 'acetaminophen'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '1000'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '18 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '18 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:43:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User entered empty.	System	17 Mar 2021 15:43:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User entered empty.	System	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:36
User entered empty.	System	17 Mar 2021 15:43:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN HUMAN, PRODUCTSYNONYM: HUMULIN R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:51
Data point term sent to Coder	System	17 Mar 2021 15:44:56
User entered 'humulin R'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:52:21
User closed query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review both ConMed and AE pages and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 12:31:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review both ConMed and AE pages and update accordingly, else clarify.' answered with 'ENTRY ERROR' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 17:43:08
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:42:59
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:08:52
User opened query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review both ConMed and AE pages and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:37:22
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:52:25
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:16:48
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'diabetes mellitus T2'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0.5'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'U/hr'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'continuous'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:52:32
User closed query 'per hospital notes start date = 15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:52:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'per hospital notes start date = 15Jan2021, please verify' answered with 'UPDATED ' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 18:01:46
User entered '15 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 18:01:37
User opened query 'per hospital notes start date = 15Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 16:09:39
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:09:13
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '18 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User entered empty.	System	17 Mar 2021 15:44:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User entered empty.	System	17 Mar 2021 15:44:40

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:00
User entered empty.	System	17 Mar 2021 15:44:40

FDA-CBER-2022-1614-0444819

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:47:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:47:44
Data point term sent to Coder	System	17 Mar 2021 15:46:58
User entered 'dilaudid'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'pancreatitis'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0.3'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '19 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '19 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:46:04

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User entered empty.	System	17 Mar 2021 15:46:04

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User entered empty.	System	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:05
User entered empty.	System	17 Mar 2021 15:46:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:15:50
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 Apr 2021 07:15:50
Data point term sent to Coder	System	09 Apr 2021 17:49:11
Coding entries removed.	Erica Osmundsen (b) (4)	09 Apr 2021 17:48:35
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:37:52
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 Mar 2021 21:37:52
Data point term sent to Coder	System	17 Mar 2021 15:47:59
User entered 'fentanyl citrate'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'pancreatitis'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '50'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'ug (ug)'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:52:51
User closed query 'per MAR = gtt, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:52:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'per MAR = gtt, please verify' answered with 'CORRECTED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 17:49:08
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 17:48:35
User opened query 'per MAR = gtt, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 16:20:17
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:19:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Transdermal (TRANSDERMAL)'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:44:53
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:44:53
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:53:03
User closed query 'please verify as fentayl gtt is not noted on MAR for 18Jan2021.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:53:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'please verify as fentayl gtt is not noted on MAR for 18Jan2021.' answered with 'ADMINISTERED AS NEEDED / PRN NOT DAILY' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 17:50:00
User opened query 'please verify as fentayl gtt is not noted on MAR for 18Jan2021.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 16:25:09
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:19:45
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User entered empty.	System	17 Mar 2021 15:47:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User entered empty.	System	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:11
User entered empty.	System	17 Mar 2021 15:47:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:20:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 11:20:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:44:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:44:18
Data point term sent to Coder	System	09 Apr 2021 19:43:07
Coding entries removed.	Erica Osmundsen (b) (4)	09 Apr 2021 19:42:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:23:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:23:34
Data point term sent to Coder	System	17 Mar 2021 15:50:02

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
User entered 'potassium chloride'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:53:20
User closed query 'please verify indication' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:53:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'please verify indication' answered with 'UPDATED PER SOURCE' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 19:42:12
User entered 'INTERMITTENT ELECTROLYTE IMBALANCES' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:42:04
User opened query 'please verify indication' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 18:36:24
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'pancreatitis'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:43:30
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 21:13:14
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 21:13:14
User entered '20' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 21:13:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '60'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mEq'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:43:19
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 21:13:14
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 21:13:14
User entered 'three times daily (TID)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 21:13:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '19 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '19 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User entered '3'	System	16 Apr 2021 21:13:14
User entered empty.	System	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User entered '1'	System	16 Apr 2021 21:13:14
User entered empty.	System	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:32
User entered '804 (804)'	System	16 Apr 2021 21:13:14
User entered empty.	System	17 Mar 2021 15:49:08

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:51:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:51:56
Data point term sent to Coder	System	17 Mar 2021 15:51:03
User entered 'colace'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'constipation'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '100'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '19 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:50:50

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User entered '2'	System	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User entered '1'	System	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:37
User entered '804 (804)'	System	17 Mar 2021 15:50:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA LAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:52:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:52:44
Data point term sent to Coder	System	17 Mar 2021 15:52:04
User entered 'senna-lax'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'constipation'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '8.6'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '19 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User entered '2'	System	17 Mar 2021 15:51:35

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User entered '1'	System	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:42
User entered '804 (804)'	System	17 Mar 2021 15:51:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:48:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:48:47
Data point term sent to Coder	System	16 Apr 2021 13:07:50
Coding entries removed.	Erica Osmundsen (b) (4)	16 Apr 2021 13:07:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:51:54
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 Apr 2021 13:51:54
Data point term sent to Coder	System	12 Apr 2021 13:29:39
Coding entries removed.	Erica Osmundsen (b) (4)	12 Apr 2021 13:29:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:53:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:53:45

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data point term sent to Coder	System	17 Mar 2021 15:53:07
User entered 'labetalol'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
User closed query 'Per CDM: Please review and confirm if this pertains to (#6) ACUTE RENAL FAILURE UNSPECIFIED' in the AE eCRF? If yes, please reconcile with corresponding CM to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 08:57:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:53:50
Query 'Per CDM: Please review and confirm if this pertains to (#6) ACUTE RENAL FAILURE UNSPECIFIED' in the AE eCRF? If yes, please reconcile with corresponding CM to maintain consistency among eCRF pages.' answered with 'CONFIRMED AND TERM UPDATED' (Site from DM).	Erica Osmundsen (b) (4)	16 Apr 2021 13:07:50
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 13:07:34
User entered 'ACUTE RENTAL FAILURE UNSPECIFIED' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 13:07:34
User opened query 'Per CDM: Please review and confirm if this pertains to (#6) ACUTE RENAL FAILURE UNSPECIFIED' in the AE eCRF? If yes, please reconcile with corresponding CM to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:00:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	12 Apr 2021 13:29:25
User entered 'ACUTE RENTAL FAILURE' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Apr 2021 13:29:25
User closed query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:21:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' answered with 'AE LOG UPDATED PER SOURCE' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 19:09:07
User opened query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:08:49
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'hypertension'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:58:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'CONFIRMED CORRECT PER Medication administration records from hospital. Medication prescribed " Trandate (LABETALOL 20MG/4ML INJ) but on each dosage, it is noted as "GAVE 10 MG".' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 19:21:44
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 02:37:43
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '10'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User closed query 'Per CDM: Please verify if this pertains to (#17) HYPERTENSION (start date 27-JAN-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:59:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per CDM: Please verify if this pertains to (#17) HYPERTENSION (start date 27-JAN-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' answered with 'UPDATED INDICATION--SUBJECT NOT DIAGNOSED W/ HYPERTENSION YET, BUT BP WAS ELEVATED SECONDARY TO ACUTE RENAL FAILURE' (Site from DM).	Erica Osmundsen (b) (4)	12 Apr 2021 13:30:25
User opened query 'Per CDM: Please verify if this pertains to (#17) HYPERTENSION (start date 27-JAN-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:21:40
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '19 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User entered empty.	System	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User entered empty.	System	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:47
User entered empty.	System	17 Mar 2021 15:52:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:54:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:54:48
Data point term sent to Coder	System	17 Mar 2021 15:54:07
User entered 'miralax'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'constipation'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '17'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'g (g)'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '21 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User entered '1'	System	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User entered '1'	System	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:52
User entered '804 (804)'	System	17 Mar 2021 15:53:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:06:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:06:44
Data point term sent to Coder	System	17 Mar 2021 16:05:35
User entered 'lantus'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'diabetes mellitus T2'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '20'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'units'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '21 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '27 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User entered '1'	System	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User entered '1'	System	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:57
User entered '804 (804)'	System	17 Mar 2021 16:05:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 16:08:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 16:08:44
Data point term sent to Coder	System	17 Mar 2021 16:07:40
User entered 'bisacodyl'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'constipation'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '10'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '21 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '21 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:06:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User entered empty.	System	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User entered empty.	System	17 Mar 2021 16:06:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:23:11
User entered empty.	System	17 Mar 2021 16:06:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:46:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:46:02
Data point term sent to Coder	System	17 Mar 2021 16:08:41
User entered 'humalog'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'DM T2'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '3'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Other (OTHER)' reason for change: Data Entry Error	Teresa Deese (b) (4)	17 Mar 2021 16:08:42
User entered 'IU (IU)'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'units' reason for change: Data Entry Error	Teresa Deese (b) (4)	17 Mar 2021 16:08:42
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'three times daily (TID)'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '21 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User entered '3'	System	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User entered '1'	System	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:52
User entered '804 (804)'	System	17 Mar 2021 16:07:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: DIAZEPAM, PRODUCTSYNONYM: VALIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:07:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:07:33
Data point term sent to Coder	System	17 Mar 2021 16:10:48
User entered 'valium'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'alcohol (ETOH) withdrawal'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '5'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '21 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '21 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User entered empty.	System	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User entered empty.	System	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:58
User entered empty.	System	17 Mar 2021 16:10:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: ROXICODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:12:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:12:44
Data point term sent to Coder	System	17 Mar 2021 16:11:52
User entered 'roxicodone'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'pancreatitis'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '5'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '21 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '2 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User entered empty.	System	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User entered empty.	System	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:04
User entered empty.	System	17 Mar 2021 16:11:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE, PRODUCTSYNONYM: CATAPRES [CLONIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:49:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:49:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 13:32:41
Coding entries removed.	Erica Osmundsen (b) (4)	12 Apr 2021 13:32:02
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE, PRODUCTSYNONYM: CATAPRES [CLONIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:11:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:11:50
Data point term sent to Coder	System	17 Mar 2021 16:12:53
User entered 'catapres'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:49
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	12 Apr 2021 13:32:02
User entered 'acute renal failure' reason for change: New Information	Erica Osmundsen (b) (4)	12 Apr 2021 13:32:02
User closed query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:15:57
Query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' answered with 'AE updated per source' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 19:23:35
User opened query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:12:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'hypertension'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0.2'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:56:09
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User closed query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "every week" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 11:14:26
Query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "every week" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'updated' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 19:23:51
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 19:23:46
User entered 'every week (QS)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:23:46
User opened query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "every week" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 02:38:08
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:56:12
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 19:23:46
User entered empty; reason for change Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:23:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'q weekly'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Transdermal (TRANSDERMAL)'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:09
User closed query 'per MAR start date = 22Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:55:07
User closed query 'Per CDM: Please verify if this pertains to (#17) HYPERTENSION (start date 27-JAN-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:01:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per CDM: Please verify if this pertains to (#17) HYPERTENSION (start date 27-JAN-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' answered with 'updated indication as the diagnosis was not made until 27jan2021 but bp elevated due to renal failure prior to diagnosis date' (Site from DM).	Erica Osmundsen (b) (4)	12 Apr 2021 13:35:15
User opened query 'Per CDM: Please verify if this pertains to (#17) HYPERTENSION (start date 27-JAN-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:18:40
Query 'per MAR start date = 22Jan2021, please verify' answered with 'confirmed' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 19:24:08
User entered '22 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:23:58
User opened query 'per MAR start date = 22Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 18:52:14
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:51:49
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '25 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:16
User closed query 'Please verify, not listed as a discharge medication' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:55:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Please verify, not listed as a discharge medication' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 19:25:22
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:25:18
User opened query 'Please verify, not listed as a discharge medication' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 16:43:39
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:19
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

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
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:56:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '09 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:25:18
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:43:21
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User entered '1'	System	09 Apr 2021 19:23:46
User entered empty.	System	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User entered '1'	System	09 Apr 2021 19:23:46
User entered empty.	System	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:10
User entered '803 (803)'	System	09 Apr 2021 19:23:46
User entered empty.	System	17 Mar 2021 16:12:40

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:15:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:15:45
Data point term sent to Coder	System	17 Mar 2021 16:14:55
User entered 'lactated ringers'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '1000'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mL (mL)'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '19 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User entered empty.	System	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User entered empty.	System	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:16
User entered empty.	System	17 Mar 2021 16:13:56

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
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: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:15:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:15:44
Data point term sent to Coder	System	17 Mar 2021 16:14:56
User entered 'pantoprazole'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'gastric ulcer'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '40'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once (ONCE)'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 15:44:53
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

FDA-CBER-2022-1614-0445088

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User entered empty.	System	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User entered empty.	System	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:21
User entered empty.	System	17 Mar 2021 16:14:44

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
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: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:23:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:23:33
Data point term sent to Coder	System	17 Mar 2021 16:15:56
User entered 'prilosec (omeprazole)'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'gastric ulcer'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '40'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '10 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	17 Mar 2021 16:15:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:27:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:27:54
Data point term sent to Coder	System	17 Mar 2021 16:23:04
Data point term sent to Coder	System	17 Mar 2021 16:19:00
User entered 'dextrose 10%/water'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	17 Mar 2021 16:22:39
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'HYPOGLYCEMIA prophylaxis' reason for change: Data Entry Error	Teresa Deese (b) (4)	17 Mar 2021 16:22:39
User entered 'hypoglycemia'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '1000'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mL (mL)'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '19 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User entered empty.	System	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User entered empty.	System	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:46
User entered empty.	System	17 Mar 2021 16:18:59

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;SODIUM CHLORIDE, PRODUCTSYNONYM: DEXTROSE 5% AND 0.9% NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:26:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:26:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	09 Apr 2021 19:42:58
Coding entries removed.	Erica Osmundsen (b) (4)	09 Apr 2021 19:42:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;SODIUM CHLORIDE, PRODUCTSYNONYM: DEXTROSE 5% AND 0.9% NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:28:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:28:51
Data point term sent to Coder	System	17 Mar 2021 16:24:04
User entered 'dextrose 5%/saline .9%'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (42)
Generated On: 09 Jun 2021 15:44:53
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:56:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 19:42:46
User entered 'INTERMITTENT ELECTROLYTE IMBALANCES' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:42:46
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '1000'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mL (mL)'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 16:24:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 16:24:03
User entered 'Intravenous Drip (INTRAVENOUS DRIP)' reason for change: Data Entry Error	Teresa Deese (b) (4)	17 Mar 2021 16:24:03
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 16:23:50
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '20 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User entered empty.	System	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User entered empty.	System	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:52
User entered empty.	System	17 Mar 2021 16:23:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN HUMAN, PRODUCTSYNONYM: HUMULIN R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:51
Data point term sent to Coder	System	17 Mar 2021 16:26:09
User entered 'humulin R'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'diabetes T2'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User closed query 'per MAR the dose was variable as based on sliding scale, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:57:10
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:57:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'per MAR the dose was variable as based on sliding scale, please verify' answered with 'CONFIRMED-SLIDING SCALE' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 18:33:19
User entered 'VARIABLE' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 18:32:18
User opened query 'per MAR the dose was variable as based on sliding scale, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 16:54:47
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:54:24
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '2'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'units'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User closed query 'per MAR q 6 hours, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:57:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:57:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'per MAR q 6 hours, please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 18:35:02
User entered 'four times daily (QID)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 18:32:43
User opened query 'per MAR q 6 hours, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 16:55:46
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:55:19
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'three times daily (TID)'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '27 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:57:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:55:51
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User entered '4'	System	09 Apr 2021 18:32:43
User entered '3'	System	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User entered '1'	System	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:40:57
User entered '804 (804)'	System	17 Mar 2021 16:25:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:02
Data point term sent to Coder	System	17 Mar 2021 16:29:11
User entered 'guaifenesin'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mucolytic- subj had pneumonia'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '200'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 16:29:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 16:29:01
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Teresa Deese (b) (4)	17 Mar 2021 16:29:01
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 16:28:52
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '2 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User entered empty.	System	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User entered empty.	System	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:03
User entered empty.	System	17 Mar 2021 16:28:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
Query 'Mar source also = Coreg, 6.25 mg po BID, 26Jan2021 before dose increase on 27Jan2021. Please verify' canceled (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:20:05
User opened query 'Mar source also = Coreg, 6.25 mg po BID, 26Jan2021 before dose increase on 27Jan2021. Please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:03:44
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:45:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:45:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:30:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:30:45
Data point term sent to Coder	System	17 Mar 2021 16:30:12
User entered 'carvedilol'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User closed query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:19:36
Query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' answered with 'AE ADDED PER SOURCE' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 19:36:14
User opened query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:15:36
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'hypertension'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '12.5'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (45)
Generated On: 09 Jun 2021 15:44:53
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:58:58
User closed query 'per MAR start date = 27Jan2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:58:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'per MAR start date = 27Jan2021, Please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 19:37:09
User entered '27 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:37:05
User opened query 'per MAR start date = 27Jan2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:01:42
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '30 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User entered '2'	System	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User entered '1'	System	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:08
User entered '804 (804)'	System	17 Mar 2021 16:29:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: COMBIVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:04:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:04:57
Data point term sent to Coder	System	09 Apr 2021 14:32:33
Coding entries removed.	Erica Osmundsen (b) (4)	09 Apr 2021 14:32:20
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: COMBIVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:24:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:24:50
Data point term sent to Coder	System	17 Mar 2021 16:32:15
User entered 'combivent nebulizer'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:59:20
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 14:32:20
User entered '1.) PNEUMONIA 2.) DYSPNEA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:32:20
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'pneumonia/dyspnea'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:59:22
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard combination dose for this medication (e.g Dose =500/2.5; Dose Unit=mcg/mg. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:03:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per DM CLR: Please review the dose recorded as this is not the standard combination dose for this medication (e.g Dose =500/2.5; Dose Unit=mcg/mg. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'corrected' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 14:33:23
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 14:33:15
User entered '500/2.5' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:33:15
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard combination dose for this medication (e.g Dose =500/2.5; Dose Unit=mcg/mg. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 02:38:41
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0.5/2.5'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:59:26
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Apr 2021 14:33:15
User entered 'MCG/MG' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 14:33:15
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mcg/mg per 3 ml'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '7 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Mar 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User entered '2'	System	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User entered '1'	System	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:14
User entered '804 (804)'	System	17 Mar 2021 16:32:01

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:59:42
User closed query 'd/C summary = Novolin 70/30, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:59:40
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
Query 'd/C summary = Novolin 70/30, please verify' answered with 'THE MEDICATION THAT SUBJECT WAS ABLE TO OBTAIN WAS HUMULIN 70/30 PER HIS REPORT AT SITE VISITS AND MED LIST EMAILED FROM SUBJECT' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 19:08:20
User opened query 'd/C summary = Novolin 70/30, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:12:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 17:11:27
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE, PRODUCTSYNONYM: HUMULIN 70/30 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:46:50
Data point term sent to Coder	System	17 Mar 2021 16:35:18
User entered 'humulin 70/30'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'diabetes T2'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '5'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Other (OTHER)'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'units'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '2'	System	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	17 Mar 2021 16:34:18

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 20:17:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 20:17:08
Data point term sent to Coder	System	17 Mar 2021 16:35:18
User entered 'albuterol HFA'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:03:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE ADDED PER SOURCE' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 19:08:38
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 02:38:59
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'dyspnea'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:14:16
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 17:12:54
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '90'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:14:17
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 17:12:55
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'ug (ug)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (48)
Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	17 Mar 2021 16:35:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	17 Mar 2021 16:35:15

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	17 Mar 2021 16:35:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:37:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:37:44
Data point term sent to Coder	System	17 Mar 2021 16:36:19
User entered 'lisinopril'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User closed query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:20:07
Query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' answered with 'AE ADDED PER SOURCE' (Site from DM).	Erica Osmundsen (b) (4)	09 Apr 2021 19:43:34
User opened query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event record that match with this condition? Kindly verify and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 09:18:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'hypertension'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '10'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (49)
Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'once daily (QD)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (49)
Generated On: 09 Jun 2021 15:44:53
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

FDA-CBER-2022-1614-0445265

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:00:01
User closed query 'source=08Mar2021 please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:59:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'source=08Mar2021 please verify' answered with 'CORRECTED PER SOURCE' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 19:44:10
User entered '08 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 19:44:03
User opened query 'source=08Mar2021 please verify' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 19:58:51
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 19:56:31
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '9 Feb 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Yes (Y)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	17 Mar 2021 16:35:47

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:38:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 16:38:45
Data point term sent to Coder	System	17 Mar 2021 16:37:20
User entered 'vancomycin'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'sepsis'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:00:11
User closed query 'MAR= 1250 mg, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:00:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Query 'MAR= 1250 mg, please verify' answered with 'done' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 15:20:16
User entered '1250' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Apr 2021 15:19:45
User opened query 'MAR= 1250 mg, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:57:54
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 19:57:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '1000'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'mg (mg)'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'Intravenous (INTRAVENOUS)'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '26 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '0'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered '29 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:39:02
User entered 'No (N)'	Teresa Deese (b) (4)	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User entered '2'	System	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User entered '1'	System	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:41:22
User entered '804 (804)'	System	17 Mar 2021 16:36:43

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:01:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:00:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:00:58
Data point term sent to Coder	System	09 Apr 2021 20:14:58
User entered 'METRONIDAZOLE'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'SEPSIS'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '500'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:13
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '24 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '24 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
User entered '2'	System	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
User entered '1'	System	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:07
User entered '804 (804)'	System	09 Apr 2021 20:14:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:02:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:53:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:53:53
Data point term sent to Coder	System	09 Apr 2021 20:16:01
User entered 'LASIX'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:07
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'LOCULATED ASCITES'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '60'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '28 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '28 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
User entered empty.	System	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
User entered empty.	System	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:13
User entered empty.	System	09 Apr 2021 20:15:50

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: CHLOROTHIAZIDE, PRODUCTSYNONYM: DIURIL [CHLOROTHIAZIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:58:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:58:00
Data point term sent to Coder	System	12 Apr 2021 13:41:03
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	12 Apr 2021 13:40:48
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'done' (Site from System).	Erica Osmundsen (b) (4)	12 Apr 2021 13:40:48
User entered 'DIURIL (chlorothiazide)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	12 Apr 2021 13:40:25
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	12 Apr 2021 12:16:55
Data point term sent to Coder	System	09 Apr 2021 20:21:09
User entered 'DIURIL'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'LOCULATED ASCITES'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '500'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:03:59
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (53)
Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '28 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '28 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	09 Apr 2021 20:20:15

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:46:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:46:55
Data point term sent to Coder	System	09 Apr 2021 20:40:41
User entered 'ZOFRAN'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:04:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'UNSPECIFIED GASTRITIS'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:01
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered '4'	(b) (4) Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:07
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	09 Apr 2021 20:40:38

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:04:54
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 Apr 2021 08:04:54
Data point term sent to Coder	System	09 Apr 2021 21:09:15
User entered 'ROCEPHIN'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:05:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'SEPSIS'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '1000'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:23
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	09 Apr 2021 21:08:23

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:51:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:51:42
Data point term sent to Coder	System	12 Apr 2021 13:44:09
User entered 'METRONIDAZOLE'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'SEPSIS'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:07:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '500'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (56)
Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:14
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:43:35

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:43:35

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:43:35

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:56:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:56:55
Data point term sent to Coder	System	12 Apr 2021 13:45:11
User entered 'AZITHROMYCIN'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:08:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'SEPSIS'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '500'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

FDA-CBER-2022-1614-0445404

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:09:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:44:33

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:51:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:51:54
Data point term sent to Coder	System	12 Apr 2021 13:46:13
User entered 'ROCEPHIN'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'SEPSIS'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '1000'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:45
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:11:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:45:24

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 11:24:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 11:24:54
Data point term sent to Coder	System	16 Apr 2021 20:27:05
Coding entries removed.	Erica Osmundsen (b) (4)	16 Apr 2021 20:26:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:08:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:08:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 13:48:15
User entered 'NOREPINEPHRINE/ DEXTROSE'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (59)
Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (59)
Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:40:03
User closed query 'please verify indication ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:40:01
Query 'please verify indication ' answered with 'CORRECTED' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 20:29:44
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:26:22
User entered 'SEPSIS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:26:22
User opened query 'please verify indication ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:13:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:08
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered '4 MG/ 250'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (59)
Generated On: 09 Jun 2021 15:44:53
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:12:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:47:31

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:59:19
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 Apr 2021 13:59:19
Data point term sent to Coder	System	12 Apr 2021 13:49:16
User entered 'ALBUTEROL SULFATE'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '180'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'ug (ug)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:48:51

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:54:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:54:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 13:51:17
User entered 'HEPARIN SODIUM'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'PROPHYLAXIS'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '5000'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:19:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'IU (IU)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:02
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:39:39
User closed query 'Mar = Q 8 hours, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:39:38
Query 'Mar = Q 8 hours, please verify' answered with 'CORRECTED' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 20:52:01
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:51:20
User entered 'three times daily (TID)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:51:20
User opened query 'Mar = Q 8 hours, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:19:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'four times daily (QID)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '3'	System	16 Apr 2021 20:51:20
User entered '4'	System	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	12 Apr 2021 13:50:17

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:39:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:39:42
Data point term sent to Coder	System	12 Apr 2021 13:52:19
User entered 'METOPROLOL TARTRATE'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'ACUTE RENAL FAILURE'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '5'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:22:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 13:51:42

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:51:42

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 13:51:42

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:03:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:03:02
Data point term sent to Coder	System	12 Apr 2021 14:02:38
User entered 'fenofibrate'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:23:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'hypertriglyceridemia'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '145'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:25:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:19
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:02:03

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:22:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:22:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 14:03:43
User entered 'midazolam HCL'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (64)
Generated On: 09 Jun 2021 15:44:53
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:26:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:38:34
User closed query 'source = concentration of 0.5mg/mL as IV drip infusion, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:38:32
Query 'source = concentration of 0.5mg/mL as IV drip infusion, please verify' answered with 'updated for clarity in source and edc per medical records' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 20:55:20
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
User entered '0.5' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
User opened query 'source = concentration of 0.5mg/mL as IV drip infusion, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:29:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '100'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:38:39
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
User entered 'Other (OTHER)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:38:40
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
User entered 'mg/mL' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:38:42
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
User entered 'other (OTHER)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:38:44
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
User entered 'continuous' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:54:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:03:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:30:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:46:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:46:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 14:05:48
User entered 'FENTANYL SODIUM CHLORIDE 20mcg / ML'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:30:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'PANCREATITIS'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:39:03
User closed query 'source = 20mcg/mL infusion, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:39:00
Query 'source = 20mcg/mL infusion, please verify' answered with 'UPDATED IN SOURCE AND EDC PER MEDICAL RECORDS FOR CLARITY OF RATE AND AMOUNT' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:41
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
User entered '20' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
User opened query 'source = 20mcg/mL infusion, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:30:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '125'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:39:05
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
User entered 'Other (OTHER)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:39:06
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
User entered 'mcg/mL' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:39:09
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
User entered 'other (OTHER)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:39:11
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
User entered 'CONTINUOUS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:56:11
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:11
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:31:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:05:25

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:08:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:08:07
Data point term sent to Coder	System	12 Apr 2021 14:06:52
User entered 'morphine sulfate'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'pancreatitis'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '2'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:30
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:32
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:06:11

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE HYDROCHLORIDE, PRODUCTSYNONYM: PRECEDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:41:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:41:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 14:08:59
User entered 'PRECEDEX/NS (DEXMEDETOMIDINE/ SODIUM CHLORIDE 400MCG/ 100 ML'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '100'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

FDA-CBER-2022-1614-0445584

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (67)
Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:08:28

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: MIDAZOLAM HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:22:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:22:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 14:10:03
User entered 'MIDAZOLAM HCL'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '2'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:33:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:04
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:09:32

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ETOMIDATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:42:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:42:03
Data point term sent to Coder	System	12 Apr 2021 14:11:04
User entered 'ETOMIDATE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '20'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (69)
Generated On: 09 Jun 2021 15:44:53
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:28
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:10:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:10:26

FDA-CBER-2022-1614-0445631

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:10:26

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:14:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:14:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 14:12:05
User entered 'DIPRIVAN 1000MG/100ML (PROPOFOL)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'PANCREATITIS'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '100'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:34:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:14
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:11:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:11:36

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:21
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROMORPHONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:19:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:19:05
Data point term sent to Coder	System	12 Apr 2021 14:18:17
User entered 'HYDROMORPHONE HCL'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'PANCREATITIS'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0.5'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (71)
Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:47:30
User closed query 'source = 15Jan2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 15:47:29
Query 'source = 15Jan2021, Please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 21:00:14
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 20:59:56
User entered '15 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 20:59:56
User opened query 'source = 15Jan2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:36:16
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:18
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:23
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:18:09

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:58:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:58:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 14:19:18
User entered 'LORAZEPAM'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (72)
Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'ACUTE HYPOXIC RESPIRATORY FAILURE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:38
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '2'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (72)
Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:41
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:19:13

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: CALCIUM GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:41:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:41:01
Data point term sent to Coder	System	12 Apr 2021 14:20:21
User entered 'CALCIUM GLUCONATE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:37:09
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'INTERMITTENT ELECTROLYTE IMBALANCE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:06
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '4'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (73)
Generated On: 09 Jun 2021 15:44:53
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:08
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'g (g)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:10
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

FDA-CBER-2022-1614-0445694

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:20
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:22
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:26
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:20:16

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:20:16

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (74)
Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:32
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM PHOSPHATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:38:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 14:38:03
Data point term sent to Coder	System	12 Apr 2021 14:22:27
User entered 'SODIUM PHOSPHATE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:36
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'INTERMITTENT ELECTROLYTE IMBALANCE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '30'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'MMOL'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:04
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:05
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	12 Apr 2021 14:21:29

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE, PRODUCTSYNONYM: DEXTROSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:09:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:09:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 14:26:42
User entered 'POTASSIUM CHLORIDE / DEXTROSE 5% / SODIUM CHLORIDE (POTASSIUM 20 MEQ/LITER; DEXTROSE 1/ NS 2)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:15
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'INTERMITTENT ELECTROLYTE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '1000'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:25
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'four times daily (QID)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:39:56
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '4'	System	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	12 Apr 2021 14:26:21

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:54:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:54:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 14:38:55
User entered 'SODIUM CHLORIDE 0.9%'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:27
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'INTERMITTENT ELECTROLYTE IMBALANCE'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:29
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '1000'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:31
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:33
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'three times daily (TID)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (76)
Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

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US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:39
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:41
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:43
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:44
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:46
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:40:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '3'	System	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	12 Apr 2021 14:38:52

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: IODINE THERAPY, ATC: IODINE THERAPY, PRODUCT: IODINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:48:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:48:34
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
Data point term sent to Coder	System	12 Apr 2021 14:42:58
User entered 'IODINE SWAB'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'INFECTION PREVENTION'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:41:57
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '2'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:42:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'SWABS PER NOSTRIL'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:35
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:37
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:40
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'Nasal (NASAL)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered empty.	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:46
User signature succeeded.	Mark McKenzie (b) (4)	12 Apr 2021 17:20:07
	(b) (4)	
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '0'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:50
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:54
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered '16 Jan 2021'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:44:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 17:20:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '2'	System	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '1'	System	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered '804 (804)'	System	12 Apr 2021 14:42:04

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: AMINO ACIDS NOS;CARBOHYDRATES NOS;ELECTROLYTES NOS, PRODUCTSYNONYM: CLINIMIX [AMINO ACIDS NOS;CARBOHYDRATES NOS;ELECTROLYTES NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 12:09:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 12:09:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:24
Data point term sent to Coder	System	16 Apr 2021 21:09:55
User entered 'Clinimax - Total parenteral nutrition'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:25
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:48:30
User entered 'pancreatitis'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:33
User entered 'varied'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:34
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:38
User entered 'mL/hr'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:36
User entered 'other (OTHER)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:41
User entered 'continuous'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (78)
Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:43
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:46
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:48
User entered '27 Jan 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

FDA-CBER-2022-1614-0445788

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:50
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:48:52
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:48:54
User entered '08 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:48:55
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	16 Apr 2021 21:08:55

FDA-CBER-2022-1614-0445793

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	16 Apr 2021 21:08:55

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:13:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:13:26
Data point term sent to Coder	System	16 Apr 2021 21:11:59
User entered 'POTASSIUM CHLORIDE'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:03
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:05
User entered 'INTERMITTENT ELECTROLYTE IMBALANCE'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:08
User entered '20'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:10
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:11
User entered 'Meq'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:49:13
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:49:17
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:19
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:20
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:25
User entered '23 Jan 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:27
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:29
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:31
User entered '23 Jan 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:33
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	16 Apr 2021 21:11:37

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:18:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:18:54
Data point term sent to Coder	System	16 Apr 2021 21:29:13
User entered 'SODIUM CHLORIDE 0.9% WEIGHT-BASED'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:42
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:43
User entered 'INTERMITTENT ELECTROLYTE IMBALANCE'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:51
User entered '2863.65'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:52
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:54
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

FDA-CBER-2022-1614-0445819

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:56
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:49:58
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:50:00
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:50:02
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:50:04
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:50:05
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:50:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:50:09
User entered '15 Jan 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:50:10
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	16 Apr 2021 21:28:53

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (80)
Generated On: 09 Jun 2021 15:44:53

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 15:44:53

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:42:58
User entered empty.	System	16 Apr 2021 21:28:53

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:44:53

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
User closed query 'Source also = Mechanical Ventilation, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:57:19
User closed query 'Also apheresis as treatment for hypertriglycerides, please verify ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:57:17
User closed query 'per source dialysis also 19-21Jan2021. Hospital records also = Ultrasound guided Paracentesis for Loculated Ascites on 27Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:57:15
Query 'Source also = Mechanical Ventilation, please verify' answered with 'added' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 12:20:00
Query 'Also apheresis as treatment for hypertriglycerides, please verify ' answered with 'added' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:57
Query 'per source dialysis also 19-21Jan2021. Hospital records also = Ultrasound guided Paracentesis for Loculated Ascites on 27Jan2021, please verify' answered with 'added' (Site from CRA).	Erica Osmundsen (b) (4)	09 Apr 2021 12:19:53
User opened query 'Source also = Mechanical Ventilation, please verify' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:24:56
User opened query 'Also apheresis as treatment for hypertriglycerides, please verify ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:38:28
User opened query 'per source dialysis also 19-21Jan2021. Hospital records also = Ultrasound guided Paracentesis for Loculated Ascites on 27Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:36:34
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:31:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	17 Mar 2021 16:37:05
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	26 Aug 2020 18:00:46

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:33:52
User entered '28 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:37:35

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:54
User entered 'decompression colonoscopy'	Teresa Deese (b) (4)	17 Mar 2021 16:37:35

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US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:33:57
User entered 'Adverse Event (AE)'	Teresa Deese (b) (4)	17 Mar 2021 16:37:35

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:44:53

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:33:59
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:37:35

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:00
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:34:08
User entered '18 Jan 2021'	Teresa Deese (b) (4)	17 Mar 2021 16:38:02

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:34:09
User entered 'dialysis'	Teresa Deese (b) (4)	17 Mar 2021 16:38:02

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:34:18
User entered 'Adverse Event (AE)'	Teresa Deese (b) (4)	17 Mar 2021 16:38:02

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:44:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:00
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:34:20
User entered empty.	Teresa Deese (b) (4)	17 Mar 2021 16:38:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	22 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:42:26
User closed query 'source = 17Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 13:42:10
Query 'source = 17Jan2021, please verify' answered with 'UPDATED ECRF' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 21:17:10
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 21:16:42
User entered '17 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 21:16:42
User opened query 'source = 17Jan2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:56:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:59
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '18 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 12:15:00

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'intubation'	Erica Osmundsen (b) (4)	09 Apr 2021 12:15:00

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:02
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:15:00

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:44:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:55:07
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:15:00

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:07
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '17 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 12:15:35

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:11
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'mechanical ventilation'	Erica Osmundsen (b) (4)	09 Apr 2021 12:15:35

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:12
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:15:35

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:44:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:17
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:15:35

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:45
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '17 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 12:16:37

FDA-CBER-2022-1614-0445849

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:47
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'aphoresis'	Erica Osmundsen (b) (4)	09 Apr 2021 12:16:37

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:49
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:16:37

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:44:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:16:37

Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 09 Jun 2021 15:44:53
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:56
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '27 Jan 2021'	Erica Osmundsen (b) (4)	09 Apr 2021 12:17:26

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:44:53

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:58
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Ultrasound guided Paracentesis'	Erica Osmundsen (b) (4)	09 Apr 2021 12:17:26

US3202085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:44:53

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:00
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4)	09 Apr 2021 12:17:26

US3202085
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 09 Jun 2021 15:44:53
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:54:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:57:03
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered empty.	Erica Osmundsen (b) (4)	09 Apr 2021 12:17:26

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:22
User entered 'USA-US128-2021-MRNA-1273-P301000010'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Mark'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'McKenzie'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered 'US'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:01:50
User entered '6'	System	02 Apr 2021 16:20:52
User entered '5'	System	23 Mar 2021 13:30:47
User entered '4'	System	18 Mar 2021 14:17:23
User entered '3'	System	08 Mar 2021 18:03:16
User entered '2'	System	01 Mar 2021 15:27:33
User entered '1'	System	22 Feb 2021 20:00:36

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:22
User entered 'USA-US128-2021-MRNA-1273-P301000010'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

FDA-CBER-2022-1614-0445875

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Mark'	System	22 Feb 2021 19:53:08

FDA-CBER-2022-1614-0445877

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'McKenzie'	System	22 Feb 2021 19:53:08

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered 'US'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:01:50
User entered '6'	System	02 Apr 2021 16:20:52
User entered '5'	System	23 Mar 2021 13:30:47
User entered '4'	System	18 Mar 2021 14:17:23
User entered '3'	System	08 Mar 2021 18:03:16
User entered '2'	System	01 Mar 2021 15:27:33
User entered '1'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:44:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered '22/Feb/2021 15:00'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:44:53

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.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:00:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 20:00:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 19:53:29

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:22
User entered 'USA-US128-2021-MRNA-1273-P301000010'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Mark'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'McKenzie'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered 'US'	System	22 Feb 2021 20:00:36

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:01:50
User entered '6'	System	02 Apr 2021 16:20:52
User entered '5'	System	23 Mar 2021 13:30:47
User entered '4'	System	18 Mar 2021 14:17:23
User entered '3'	System	08 Mar 2021 18:03:16
User entered '2'	System	01 Mar 2021 15:27:33
User entered '1'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:44:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
User entered '01/Mar/2021 10:27'	(b) (4) System	01 Mar 2021 15:27:33

Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 15:44:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 18:02:47
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:27:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 15:27:33
User entered '1' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 15:27:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 20:00:36

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:22
User entered 'USA-US128-2021-MRNA-1273-P301000010'	System	22 Feb 2021 19:53:08

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Mark'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'McKenzie'	System	22 Feb 2021 19:53:08

FDA-CBER-2022-1614-0445906

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered 'US'	System	22 Feb 2021 20:00:36

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:01:50
User entered '6'	System	02 Apr 2021 16:20:52
User entered '5'	System	23 Mar 2021 13:30:47
User entered '4'	System	18 Mar 2021 14:17:23
User entered '3'	System	08 Mar 2021 18:03:16
User entered '2'	System	01 Mar 2021 15:27:33
User entered '1'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:44:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
User entered '08/Mar/2021 13:03'	(b) (4) System	08 Mar 2021 18:03:16

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:44:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:30:51
User entered '1'	(b) (4), (b) (6)	08 Mar 2021 18:03:16

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:22
User entered 'USA-US128-2021-MRNA-1273-P301000010'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Mark'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'McKenzie'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered 'US'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:01:50
User entered '6'	System	02 Apr 2021 16:20:52
User entered '5'	System	23 Mar 2021 13:30:47
User entered '4'	System	18 Mar 2021 14:17:23
User entered '3'	System	08 Mar 2021 18:03:16
User entered '2'	System	01 Mar 2021 15:27:33
User entered '1'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:44:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
User entered '18/Mar/2021 10:17'	(b) (4) System	18 Mar 2021 14:17:23

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 15:44:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:30:51
User entered '1'	(b) (4), (b) (6)	18 Mar 2021 14:17:23

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:22
User entered 'USA-US128-2021-MRNA-1273-P301000010'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

FDA-CBER-2022-1614-0445930

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Mark'	System	22 Feb 2021 19:53:08

FDA-CBER-2022-1614-0445933

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'McKenzie'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered 'US'	System	22 Feb 2021 20:00:36

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:01:50
User entered '6'	System	02 Apr 2021 16:20:52
User entered '5'	System	23 Mar 2021 13:30:47
User entered '4'	System	18 Mar 2021 14:17:23
User entered '3'	System	08 Mar 2021 18:03:16
User entered '2'	System	01 Mar 2021 15:27:33
User entered '1'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:44:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
User entered '23/Mar/2021 09:30'	(b) (4) System	23 Mar 2021 13:30:47

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:44:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 13:30:51
User entered '1'	(b) (4), (b) (6)	23 Mar 2021 13:30:47

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:22
User entered 'USA-US128-2021-MRNA-1273-P301000010'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Mark'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'McKenzie'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered 'US'	System	22 Feb 2021 20:00:36

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:01:50
User entered '6'	System	02 Apr 2021 16:20:52
User entered '5'	System	23 Mar 2021 13:30:47
User entered '4'	System	18 Mar 2021 14:17:23
User entered '3'	System	08 Mar 2021 18:03:16
User entered '2'	System	01 Mar 2021 15:27:33
User entered '1'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:44:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '02/Apr/2021 12:20'	System	02 Apr 2021 16:20:52

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:44:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:01:13
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
User entered '1'	(b) (4), (b) (6)	02 Apr 2021 16:20:52

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:22
User entered 'USA-US128-2021-MRNA-1273-P301000010'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Yes (Y)'	System	22 Feb 2021 19:53:08

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'No (N)'	System	22 Feb 2021 19:53:08

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'Mark'	System	22 Feb 2021 19:53:08

FDA-CBER-2022-1614-0445961

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 19:53:35
User entered 'McKenzie'	System	22 Feb 2021 19:53:08

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 13:51:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:27:15
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:46:52
User entered 'US'	System	22 Feb 2021 20:00:36

US3202085
Folder: SAE USA-US128-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:44:53
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:01:50
User entered '6'	System	02 Apr 2021 16:20:52
User entered '5'	System	23 Mar 2021 13:30:47
User entered '4'	System	18 Mar 2021 14:17:23
User entered '3'	System	08 Mar 2021 18:03:16
User entered '2'	System	01 Mar 2021 15:27:33
User entered '1'	System	22 Feb 2021 20:00:36

US3202085

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:44:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '12/Apr/2021 14:01'	System	12 Apr 2021 14:01:50

Folder: SAE USA-US128-2021-MRNA-1273-P301000010

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:44:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:37:42
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	12 Apr 2021 18:08:40
User entered '1'	(b) (4), (b) (6)	12 Apr 2021 14:01:50