

US3082081 (Prod: Trial Management Associates LLC - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:03:57

All time stamps listed in this document are displayed in GMT

US3082081

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

Participant ID

US3082081

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

US3082081

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3082081

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3082081

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3082081

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3082081

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Were any significant conditions reported?

Yes ☒

No ☐

US3082081

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Condition	SKIN MELANOMA LEFT ARM
Start date (dd MMM yyyy)	UN JAN 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3082081

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Condition	SQUAMOUS CELL MELANOMA RIGHT FINGER
Start date (dd MMM yyyy)	UN FEB 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2015
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	FEB 2015
Stop Year (derived)	2015

US3082081

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Condition	ESOPHAGITIS
Start date (dd MMM yyyy)	UN JAN 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3082081

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:25 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 09:25
Height (<i>xxx.x</i>)	75 in
Weight (<i>xxx.x</i>)	233.2 lb
BMI (<i>xxx.x</i>)	29.20895 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082081

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3082081

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 186843

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Height	ND - Not Done
Weight	ND - Not Done

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	9:25 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 9:25
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:34
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3082081

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

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.

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 10:03 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 10:03

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

US3082081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 AUG 2020
Collection time (00:00-23:59)	09:01 (24 HR)
Collection date and time (derived)	21 AUG 2020 09:01

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:10	21 AUG 2020 09:10
Nasopharyngeal Swab 2	No		

US3082081

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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

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

21 AUG 2020 10:23

PC Close Date & Time

21 AUG 2020 12:53

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp	21 AUG 2020 13:58
PC Open Date & Time	21 AUG 2020 13:48
PC Close Date & Time	22 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 AUG 2020 19:40

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 16:12

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

25 AUG 2020 11:00

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 22:58

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:09

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:07

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 ☐

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

21 AUG 2020 10:23

PC Close Date & Time

21 AUG 2020 12:53

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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

4

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

21 AUG 2020 20:47

PC Open Date & Time

21 AUG 2020 13:48

PC Close Date & Time

22 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 18:54

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 16:10

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 11:01

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 22:58

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:09

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:07

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 ☐

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

21 AUG 2020 10:23

PC Close Date & Time

21 AUG 2020 12:53

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 ☐

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 20:30
PC Open Date & Time	21 AUG 2020 13:48
PC Close Date & Time	22 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 ☒

PRODUCTION RELEASE (v12.003

44 of 2525

EAB) (1725)

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:55
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

46 of 2525

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 16:10
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

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 ☒

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 11:01
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2525

EAB) (1725)

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 22:58
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

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 ☒

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:10
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

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 ☒

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:08
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3082081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	09:53 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:53
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:08
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3082081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 10:37 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 10:37

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

US3082081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	10:19 (24 HR)
Collection date and time (derived)	21 SEP 2020 10:19

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:22	21 SEP 2020 10:22
Nasopharyngeal Swab 2	No		

US3082081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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

21 SEP 2020 11:10

PC Open Date & Time

21 SEP 2020 10:57

PC Close Date & Time

21 SEP 2020 13:27

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	22 SEP 2020 07:15
PC Open Date & Time	21 SEP 2020 14:22
PC Close Date & Time	22 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

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

22 SEP 2020 19:32

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 17:32

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 13:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

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

25 SEP 2020 16:20

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 20:33

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 12:20

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 11:10

PC Open Date & Time

21 SEP 2020 10:57

PC Close Date & Time

21 SEP 2020 13:27

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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

6

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

22 SEP 2020 07:17

PC Open Date & Time

21 SEP 2020 14:22

PC Close Date & Time

22 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

6

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 19:33

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 17:33

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 13:44

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 16:20

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 20:34

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 12:21

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 ☐

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 11:11
PC Open Date & Time	21 SEP 2020 10:57
PC Close Date & Time	21 SEP 2020 13:27

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 ☐

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 07:18
PC Open Date & Time	21 SEP 2020 14:22
PC Close Date & Time	22 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 ☒

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 19:34
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

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 ☒

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 17:34
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

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 ☒

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 13:45
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

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 ☒

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 16:21
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

98 of 2525

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 20:34
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

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 ☒

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:21
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3082081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	09:43 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 09:43
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3082081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	10:17 (24 HR)
Collection date and time (derived)	19 OCT 2020 10:17

US3082081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:20

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 OCT 2020 14:00:05
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 22:16:03

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

04 NOV 2020 15:01:53

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

19 NOV 2020 15:54:53

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 14:33:07
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

30 NOV 2020 23:26:40

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

06 DEC 2020 17:40:00

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

14 DEC 2020 22:33:30

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

21 DEC 2020 21:00:26

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

27 DEC 2020 08:50:05

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

04 JAN 2021 10:32:44

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

10 JAN 2021 19:34:34

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 10:40:25

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 08:49:28

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 16:50:06

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 15:05:32

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 15:50:12
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 10:42:01

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 23:02:42
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 09:33:27
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

14 MAR 2021 14:46:39

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

21 MAR 2021 13:43:46

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

28 MAR 2021 14:38:33

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 16:00:08
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

11 APR 2021 00:16:23

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

18 APR 2021 15:25:52

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

25 APR 2021 20:04:14

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

03 MAY 2021 14:21:35

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	23 MAY 2021 00:01
Patient Cloud Close Date & Time	27 MAY 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	30 MAY 2021 00:01
Patient Cloud Close Date & Time	03 JUN 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	19 AUG 2021 23:59
---	-------------------

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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 ☐

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	31 OCT 2021 00:01
Patient Cloud Close Date & Time	04 NOV 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	13 FEB 2022 00:01
Patient Cloud Close Date & Time	17 FEB 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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):

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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 ☐

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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):

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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

Date and time of submission

Patient Cloud Open Date & Time	23 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	27 OCT 2022 23:59
---	-------------------

US3082081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:03:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 22:29:01

US3082081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:17

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:17

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:17

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3082081

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:48:19

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:22:12

Generated On: 09 Jun 2021 15:03:57

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

Visit date (dd MMM yyyy)	19 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 12:22:12

Generated On: 09 Jun 2021 15:03:57

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) _____

US3082081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:22:12

Generated On: 09 Jun 2021 15:03:57

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.

US3082081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 12:22:12

Generated On: 09 Jun 2021 15:03:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 MAR 2021

Collection time (00:00-23:59)

11:13 (24 HR)

Collection date and time (derived)

19 MAR 2021 11:13

US3082081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 12:22:12

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3082081

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:03:57

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3082081

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

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

Visit date (dd MMM yyyy)	25 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3082081

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 12:22:12

Generated On: 09 Jun 2021 15:03:57

Date of updated informed consent (dd MMM yyyy) 25 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 25 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3082081

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

Height	74.0 in
Weight	221.0 lb

US3082081

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

Height	74.0 in
Weight	221.0 lb
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 JAN 2021
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 10:19
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3082081

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

Height	74.0 in
Weight	221.0 lb
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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	

US3082081

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 JAN 2021

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

US3082081

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 12:22:12

Generated On: 09 Jun 2021 15:03:57

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

PARTICIPANT RECEIVED 2 DOSES OF MRNA

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3082081

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00-23:59)	10:50 (24 HR)
Collection date and time (derived)	25 JAN 2021 10:50

US3082081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	10:53
Collection Date and Time (derived)	25 JAN 2021 10:53

US3082081

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 12:22:12

Generated On: 09 Jun 2021 15:03:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082081

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 17:48:15

Generated On: 09 Jun 2021 15:03:57

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

AEID

Adverse event

BURSITIS [RIGHT
ARM/SHOULDER]

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)

10 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

324 of 2525

EAB) (1725)

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

AEID	USA-US114-2020-MRNA-1273-P30 1000004
Adverse event	CHOLECYSTITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	05 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

326 of 2525

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

SUBJECT HAD ACUTE ONSET OF EPIGASTRIC ABDOMINAL PAIN, NAUSEA AND VOMITING ON 02OCT2020. ABDOMEN CT WITH IV CONTRAST SHOWED THE GALLBLADDER MILDLY DISTENDED WITH SLIGHT INFILTRATION OF SURROUNDING FAT, WHICH SUGGESTED CHOLECYSTITIS. LABS COLLECTED ON 02OCT2020 SHOWED ELEVATED ALKALINE PHOSPHATASE (RESULT: 123, REFERENCE RANGE 46-116 U/L) AND ELEVATED BILIRUBIN, DIRECT (RESULT: 0.6, REFERENCE RANGE <=0.3 MG/DL) AND ELEVATED BILIRUBIN, TOTAL (RESULT: 1.6, REFERENCE RANGE 0.3-1.2 MG/DL) WHICH CAN BE INDICATIVE OF GALLBLADDER DISEASE. IT WAS DETERMINED LAPAROSCOPIC CHOLESYSTECTOMY SHOULD BE DONE. PATIENT TOLERATED IT WELL AND PAIN WAS CONTROLLED. SUBJECT WAS DISCHARGED ON 05OCT2020 AT 1800. THE PATIENT IS A MALE, NON-OBESE PATIENT, WITH NO HISTORY OF DIABETES OR OTHER RISK FACTORS PRESENT FOR CHOLECYSTITIS. A COVID TEST WAS NOT PERFORMED DURING HOSPITALIZATION.

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

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

AEID	
Adverse event	HIVES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	05 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

329 of 2525

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAD HIVES AND HE TOOK BENADRYL AND THEY RESOLVED
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)	

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

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)

5 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)

4 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

331 of 2525

EAB) (1725)

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Feb 2021 17:48:14

Generated On: 09 Jun 2021 15:03:57

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

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

Yes ☒

No ☐

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

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication DEXILANT

Prophylaxis Yes ☐
No ☒

Indication ESOPHSGITIS

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

334 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

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 ☐

PRODUCTION RELEASE (v12.003

336 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 22 AUG 2020		
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication GENERAL PAIN PREVENTATIVE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication R ARM/SHOULDER BURSITIS

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

340 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication R ARM/SHOULDER BURSITIS

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

TITRATED 6 DAYS - 6 : 5 : 4 : 3 : 2 : 1

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

342 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication STEROID SHOT

Prophylaxis Yes ☐
No ☒

Indication R ARM/SHOULDER BURSITIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

344 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication HIVES (ARMS & LEGS)

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

346 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN RELIEVER FOR
CHOLECYSTITIS

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

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN RELIEVER FOR
CHOLECYSTITIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

350 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication SENNOSIDES

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 ☐

PRODUCTION RELEASE (v12.003

352 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication IOPAMIDOL

Prophylaxis Yes ☒
No ☐

Indication CONTRAST AGENT

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication HYOSCYAMINE

Prophylaxis Yes ☐
No ☒

Indication CHOLECYSTITIS

Dose per administration 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

356 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication CEFOTETAN

Prophylaxis Yes ☒
No ☐

Indication AE #2 (CHOLECYSTITIS)

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 3 OCT 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication LIDOCAINE VISCOUS

Prophylaxis Yes ☐
No ☒

Indication LOCAL ANESTHETIC

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

360 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication ENOXAPARIN LOVENOX

Prophylaxis Yes ☒
No ☐

Indication THROMBOSIS PROPHYLAXIS
(FROM SAE)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication HYDROMORPHONE DILAUDID

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN FROM
CHOLECYSTITIS (FROM SAE)

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

SEVEN TIMES

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

364 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	2 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication PROMETHAZINE

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PROPHYLAXIS (FROM
SAE)

Dose per administration 6.25

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication ALUMINUM/MAGNESIUM/SIME
THICONE (MAALOX)

Prophylaxis Yes ☐
No ☒

Indication AE #2 [CHOLECYSTITIS]

Dose per administration 200/200/20

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN FROM
CHOLECYSTITIS (FROM SAE)

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

TWICE

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	2 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication ENOXAPARIN LOVENOX

Prophylaxis Yes ☒
No ☐

Indication THROMBOSIS PROPHYLAXIS
(FROM SAE)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication HYDROMORPHONE DILAUDID

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN FROM
CHOLECYSTITIS (FROM SAE)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	3 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN (FROM SAE)

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 ☐

PRODUCTION RELEASE (v12.003

376 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANESTHESIA (FROM
CHOLECYSTECTOMY)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	3 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN FROM
CHOLECYSTITIS (FROM SAE)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication LIDOCANE 1%, BUPRIVICANE
.25%

Prophylaxis Yes ☐
No ☒

Indication LOCAL (ABDOMIN)
ANESTHESIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	3 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		3 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication AE #2 [CHOLECYSTITIS]

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)

384 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication AE #2 [CHOLECYSTITIS]

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

386 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIOLYTIC (ANXIETY)

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

388 of 2525

EAB) (1725)

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 05 Mar 2021 16:09:37

Generated On: 09 Jun 2021 15:03:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 4 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3082081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3082081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
3 OCT 2020	CHOLECYSTECTOMY	Adverse Event	

US3082081

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:03:57

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

US3082081

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:57

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 ☐

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

SAEID	USA-US114-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

SAEID	USA-US114-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	06/OCT/2020 14:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

SAEID	USA-US114-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	07/OCT/2020 14:42
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

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

SAEID	USA-US114-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	13/OCT/2020 09:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

SAEID	USA-US114-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	14/OCT/2020 08:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

SAEID	USA-US114-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/OCT/2020 09:20
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

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

SAEID	USA-US114-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/OCT/2020 15:54
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

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

SAEID	USA-US114-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/NOV/2020 16:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Data signed: (b) (4) 19 Feb 2021 17:48:16

Generated On: 09 Jun 2021 15:03:57

SAEID	USA-US114-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/NOV/2020 10:02
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

US3082081 (Prod: Trial Management Associates LLC - ERN - PPDS)

US3082081

Form: Participant Creation

Generated On: 09 Jun 2021 15:03:57

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'US3082081'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 12:44:55

US3082081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:04

US3082081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 12:44:56

US3082081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Clinic (Clinic)'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:04

US3082081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'SCRN'	System	21 Aug 2020 13:32:04

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 12:44:57

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '66'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'YEARS'	System	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered '66'	System	21 Aug 2020 13:36:16

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Male (M)'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'I'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:57

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 13:32:29

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Aug 2020'	Alice Cipollini (b) (4)	21 Aug 2020 13:36:16

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'Aug 2020'	System	21 Aug 2020 13:36:16

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered '2020'	System	21 Aug 2020 13:36:16

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Amendment 3 (3)'	Alice Cipollini (b) (4)	21 Aug 2020 13:36:16

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 13:36:16

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 13:36:16

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 13:36:16

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 13:36:16

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 12:44:56

US3082081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:57

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'I'	System	21 Aug 2020 13:36:41

US3082081

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 13:36:41

US3082081

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:03:57

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 13:59:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Alice Cipollini (b) (4)	21 Aug 2020 13:59:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	21 Aug 2020 13:59:16
	Alice Cipollini (b) (4)	21 Aug 2020 13:59:16
	(b) (4)	

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Skin melanoma - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 09:32:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 09:32:20
Data point term sent to Coder	System	21 Aug 2020 14:05:20
User entered 'Skin Melanoma Left Arm'	Alice Cipollini (b) (4)	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'UN Jan 2013'	Alice Cipollini (b) (4)	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'UN Jan 2013'	Alice Cipollini (b) (4)	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'Jan 2013'	System	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered '2013'	System	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'Jan 2013'	System	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered '2013'	System	21 Aug 2020 14:04:56

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 09:31:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 09:31:20
Data point term sent to Coder	System	21 Aug 2020 14:06:21
User entered 'Squamous Cell Melanoma Right Finger'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'UN Feb 2015'	Alice Cipollini (b) (4)	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'UN Feb 2015'	Alice Cipollini (b) (4)	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'Feb 2015'	System	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered '2015'	System	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'Feb 2015'	System	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered '2015'	System	21 Aug 2020 14:06:11

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Oesophagitis (excl infective), PT: Oesophagitis, LLT: Esophagitis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:09:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:09:19
Data point term sent to Coder	System	21 Aug 2020 14:08:25
User entered 'Esophagitis'	Alice Cipollini (b) (4)	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'UN Jan 2016'	Alice Cipollini (b) (4)	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'Jan 2016'	System	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered '2016'	System	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered empty.	System	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered empty.	System	21 Aug 2020 14:07:25

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Aug 2020'	Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '09:25'	Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered '21 Aug 2020 09:25'	System	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '75' in	(b) (4) Alice Cipollini (b) (4)	21 Aug 2020 14:02:26
DataPoint set to visible.	(b) (4) System	21 Aug 2020 13:36:41

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '233.2' lb	(b) (4) Alice Cipollini (b) (4)	21 Aug 2020 14:02:26
DataPoint set to visible.	(b) (4) System	21 Aug 2020 13:36:41

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
Amendment Manager: User entered '29.20895'	System	17 Sep 2020 00:17:40
User entered '29.2'	System	21 Aug 2020 14:02:26
DataPoint set to visible.	System	21 Aug 2020 13:36:41

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'kg/m2'	System	21 Aug 2020 14:02:26
DataPoint set to visible.	System	21 Aug 2020 13:36:41

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4)	20 Nov 2020 16:17:34
User entered 'Other (Other)'	Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'bpm'	System	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	(b) (4) Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'breaths/min'	System	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'mmHg'	System	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User entered 'mmHg'	System	21 Aug 2020 14:02:26

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55

US3082081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55

US3082081

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 14:07:51

US3082081

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '21 Aug 2020' reason for change: Data Entry Error	System	21 Aug 2020 14:08:05
User opened query 'Future date has been entered. Please correct.' (Site from System).	Alice Cipollini (b) (4)	21 Aug 2020 14:08:05
User entered '21 Aug 2021'	(b) (4)	
	System	21 Aug 2020 14:07:51
	Alice Cipollini (b) (4)	21 Aug 2020 14:07:51
	(b) (4)	

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

[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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

[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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

[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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	(b) (4) Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

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 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'I'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '0'	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:17:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 14:09:52

US3082081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 14:11:33

US3082081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Aug 2020'	Alice Cipollini (b) (4)	21 Aug 2020 14:11:33

US3082081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Clinic (Clinic)'	Alice Cipollini (b) (4)	21 Aug 2020 14:11:33

US3082081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'VISIT1'	System	21 Aug 2020 14:11:33

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:57

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 13:29:13

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:57

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '186843'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 13:29:13

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:57

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 13:29:13

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:57

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 13:38:03

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:57

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 13:38:03

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:57

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 13:38:03

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:57

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 13:38:03

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:57

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 13:38:03

US3082081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:57

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	(b) (4) Erin Harrelson (b) (4)	22 Sep 2020 17:16:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 01:55:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:55:43

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	(b) (4) Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User accepted default value 'Pre-Dose (PREDOSE)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Aug 2020'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '9:25'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Aug 2020 9:25'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '97.9' F	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Oral (Oral)'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '87'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'bpm'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '17'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'breaths/min'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '125'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '76'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered missing code ND - Not Done.	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User accepted default value 'Post-Dose (POSTDOSE)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Aug 2020'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '10:34'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Aug 2020 10:34'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '97.8' F	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Oral (Oral)'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '79'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'bpm'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '18'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'breaths/min'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '138'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '76'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	21 Aug 2020 14:44:20

US3082081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Morgan Mathis (b) (4)	20 Nov 2020 16:22:07
User entered 'Yes (Y)'	(b) (4)	
	Alice Cipollini (b) (4)	21 Aug 2020 14:17:02
	(b) (4)	

US3082081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4)	20 Nov 2020 16:22:07
User entered '21 Aug 2020'	Alice Cipollini (b) (4)	21 Aug 2020 14:17:02

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Aug 2020'	Alice Cipollini (b) (4)	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '10:03'	Alice Cipollini (b) (4)	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Aug 2020 10:03'	System	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Left Arm (LEFT ARM)'	Alice Cipollini (b) (4)	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'ONCE'	System	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 14:10:25

US3082081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 14:17:41

US3082081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Aug 2020'	Alice Cipollini (b) (4)	21 Aug 2020 14:17:41

US3082081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '09:01'	Alice Cipollini (b) (4)	21 Aug 2020 14:17:41

US3082081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Aug 2020 09:01'	System	21 Aug 2020 14:17:41

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:03:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Aug 2020'	Alice Cipollini (b) (4)	21 Aug 2020 14:18:01

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:18:01

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 14:18:01

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '09:10'	Alice Cipollini (b) (4)	21 Aug 2020 14:18:01

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Aug 2020 09:10'	System	21 Aug 2020 14:18:01

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:18:01

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Alice Cipollini (b) (4)	21 Aug 2020 14:18:01

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	21 Aug 2020 14:18:01

US3082081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered empty.	System	21 Aug 2020 14:18:01

US3082081

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	21 Aug 2020 14:44:29

US3082081

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	21 Aug 2020 14:44:29

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Aug 2020 10:23'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Aug 2020 12:53'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T13:58:05', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd8cc7a96-b267-4105-b598-82f8f8b723ed' User entered 'Yes (Y)'	System	21 Aug 2020 17:58:43
	System	21 Aug 2020 17:58:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T13:58:20', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd8cc7a96-b267-4105-b598-82f8f8b723ed' User entered '97.1'	System	21 Aug 2020 17:58:43
	System	21 Aug 2020 17:58:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T13:58:26', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd8cc7a96-b267-4105-b598-82f8f8b723ed'	System	21 Aug 2020 17:58:43
User entered 'No (N)'	System	21 Aug 2020 17:58:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T13:58:42', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd8cc7a96-b267-4105-b598-82f8f8b723ed'	System	21 Aug 2020 17:58:43
User entered '21 Aug 2020 13:58'	System	21 Aug 2020 17:58:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Aug 2020 13:48'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 2'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T19:39:45', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '876e7b40-b996-463d-89e3-f4cdb3ddc99c' User entered 'Yes (Y)'	System	22 Aug 2020 23:40:23
	System	22 Aug 2020 23:40:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T19:39:53', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '876e7b40-b996-463d-89e3-f4cdb3ddc99c' User entered '97.1'	System	22 Aug 2020 23:40:23
	System	22 Aug 2020 23:40:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T19:40:01', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '876e7b40-b996-463d-89e3-f4cdb3ddc99c'	System	22 Aug 2020 23:40:23
User entered 'Yes (Y)'	System	22 Aug 2020 23:40:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient was contacted and details are recorded.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 08:04:14
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Ayssa Valente (b) (4)	24 Aug 2020 16:06:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T19:40:09', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '876e7b40-b996-463d-89e3-f4cdb3ddc99c'	(b) (4)	
User entered '1'	System	22 Aug 2020 23:40:23
	System	22 Aug 2020 23:40:23
	System	22 Aug 2020 23:40:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T19:40:09', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '876e7b40-b996-463d-89e3-f4cdb3ddc99c' User entered '0'	System	22 Aug 2020 23:40:23
	System	22 Aug 2020 23:40:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T19:40:21', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '876e7b40-b996-463d-89e3-f4cdb3ddc99c'	System	22 Aug 2020 23:40:23
User entered '22 Aug 2020 19:40'	System	22 Aug 2020 23:40:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 3'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:12:09', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '43647122-b0b4-4689-b8e9-d7643e77378d'	System	23 Aug 2020 20:12:28
User entered 'Yes (Y)'	System	23 Aug 2020 20:12:28

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:12:15', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '43647122-b0b4-4689-b8e9-d7643e77378d' User entered '97.7'	System	23 Aug 2020 20:12:28
	System	23 Aug 2020 20:12:28

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:12:22', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '43647122-b0b4-4689-b8e9-d7643e77378d'	System	23 Aug 2020 20:12:28
User entered 'No (N)'	System	23 Aug 2020 20:12:28

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:12:26', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '43647122-b0b4-4689-b8e9-d7643e77378d'	System	23 Aug 2020 20:12:28
User entered '23 Aug 2020 16:12'	System	23 Aug 2020 20:12:28

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 4'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:00:05', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ff232823-ae30-4b48-86eb-05638fe869ff'	System	25 Aug 2020 15:00:43
User entered 'Yes (Y)'	System	25 Aug 2020 15:00:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:00:18', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ff232823-ae30-4b48-86eb-05638fe869ff' User entered '97.7'	System	25 Aug 2020 15:00:43
	System	25 Aug 2020 15:00:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:00:30', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ff232823-ae30-4b48-86eb-05638fe869ff'	System	25 Aug 2020 15:00:43
User entered 'Yes (Y)'	System	25 Aug 2020 15:00:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient was contacted about medication details. Taking advil as needed for pain from falling. ' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 09:42:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Erin Harrelson (b) (4)	25 Aug 2020 16:30:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:00:35', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ff232823-ae30-4b48-86eb-05638fe869ff'	(b) (4)	
User entered '1'	System	25 Aug 2020 15:00:43
	System	25 Aug 2020 15:00:43
	System	25 Aug 2020 15:00:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:00:35', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ff232823-ae30-4b48-86eb-05638fe869ff' User entered '0'	System	25 Aug 2020 15:00:43
	System	25 Aug 2020 15:00:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:00:41', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ff232823-ae30-4b48-86eb-05638fe869ff'	System	25 Aug 2020 15:00:43
User entered '25 Aug 2020 11:00'	System	25 Aug 2020 15:00:43

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 5'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:57:14', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '67b25e7c-0ed6-4d38-9be1-2bc669afd5aa' User entered 'Yes (Y)'	System	26 Aug 2020 02:58:08
	System	26 Aug 2020 02:58:08

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:57:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '67b25e7c-0ed6-4d38-9be1-2bc669afd5aa' User entered '98.1'	System	26 Aug 2020 02:58:08
	System	26 Aug 2020 02:58:08

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:57:58', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '67b25e7c-0ed6-4d38-9be1-2bc669afd5aa'	System	26 Aug 2020 02:58:08
User entered 'No (N)'	System	26 Aug 2020 02:58:08

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:03', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '67b25e7c-0ed6-4d38-9be1-2bc669afd5aa'	System	26 Aug 2020 02:58:08
User entered '25 Aug 2020 22:58'	System	26 Aug 2020 02:58:08

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 6'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:06', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '892eac7e-17b2-4b57-a02c-94fb74e3730c' User entered 'Yes (Y)'	System	26 Aug 2020 16:09:23
	System	26 Aug 2020 16:09:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:11', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '892eac7e-17b2-4b57-a02c-94fb74e3730c' User entered '97.5'	System	26 Aug 2020 16:09:23
	System	26 Aug 2020 16:09:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:15', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '892eac7e-17b2-4b57-a02c-94fb74e3730c'	System	26 Aug 2020 16:09:23
User entered 'No (N)'	System	26 Aug 2020 16:09:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:19', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '892eac7e-17b2-4b57-a02c-94fb74e3730c' User entered '26 Aug 2020 12:09'	System	26 Aug 2020 16:09:23
	System	26 Aug 2020 16:09:23

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 7'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:06:54', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '8e63e928-01b8-4936-9cf2-696fd5a68f4f' User entered 'Yes (Y)'	System	27 Aug 2020 16:07:20
	System	27 Aug 2020 16:07:20

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '8e63e928-01b8-4936-9cf2-696fd5a68f4f' User entered '97.5'	System	27 Aug 2020 16:07:20
	System	27 Aug 2020 16:07:20

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:03', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '8e63e928-01b8-4936-9cf2-696fd5a68f4f' User entered 'No (N)'	System	27 Aug 2020 16:07:20
	System	27 Aug 2020 16:07:20

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:08', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '8e63e928-01b8-4936-9cf2-696fd5a68f4f' User entered '27 Aug 2020 12:07'	System	27 Aug 2020 16:07:20
	System	27 Aug 2020 16:07:20

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Aug 2020 10:23'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Aug 2020 12:53'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:33:13', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3df4fddf-ef32-4656-9759-41e53152955d'	System	22 Aug 2020 00:47:58
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 00:47:58

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:33:18', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3df4fddf-ef32-4656-9759-41e53152955d'	System	22 Aug 2020 00:47:58
User entered 'No (N)'	System	22 Aug 2020 00:47:58

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:33:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3df4dddf-ef32-4656-9759-41e53152955d' User entered 'Yes (Y)'	System	22 Aug 2020 00:47:58
	System	22 Aug 2020 00:47:58

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:47:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3df4dddf-ef32-4656-9759-41e53152955d' User entered '4'	System	22 Aug 2020 00:47:58
	System	22 Aug 2020 00:47:58

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:47:41', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3df4dddf-ef32-4656-9759-41e53152955d'	System	22 Aug 2020 00:47:58
User entered 'None (1)'	System	22 Aug 2020 00:47:58

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:47:55', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3df4fddf-ef32-4656-9759-41e53152955d' User entered '21 Aug 2020 20:47'	System	22 Aug 2020 00:47:58
	System	22 Aug 2020 00:47:58

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Aug 2020 13:48'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 2'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Changed date to reconcile with diary.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:12:24
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.'	Alice Cipollini (b) (4)	09 Sep 2020 13:13:52
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 11:46:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:53:32', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2d88234f-7375-4aa1-a678-a30e78e5cee2'	System	22 Aug 2020 22:54:21
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Aug 2020 22:54:21

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:53:36', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2d88234f-7375-4aa1-a678-a30e78e5cee2'	System	22 Aug 2020 22:54:21
User entered 'No (N)'	System	22 Aug 2020 22:54:21

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:53:40', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2d88234f-7375-4aa1-a678-a30e78e5cee2' User entered 'Yes (Y)'	System	22 Aug 2020 22:54:21
	System	22 Aug 2020 22:54:21

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:53:56', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2d88234f-7375-4aa1-a678-a30e78e5cee2' User entered '2'	System	22 Aug 2020 22:54:21
	System	22 Aug 2020 22:54:21

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:54:04', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2d88234f-7375-4aa1-a678-a30e78e5cee2' User entered 'None (1)'	System	22 Aug 2020 22:54:21
	System	22 Aug 2020 22:54:21

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:54:20', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2d88234f-7375-4aa1-a678-a30e78e5cee2' User entered '22 Aug 2020 18:54'	System	22 Aug 2020 22:54:21
	System	22 Aug 2020 22:54:21

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 3'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:09:35', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '227c3aae-fd8a-4d1f-a6fd-c091c8b474a1'	System	23 Aug 2020 20:10:16
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 20:10:16

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:09:39', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '227c3aae-fd8a-4d1f-a6fd-c091c8b474a1' User entered 'No (N)'	System	23 Aug 2020 20:10:16
	System	23 Aug 2020 20:10:16

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:09:54', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '227c3aae-fd8a-4d1f-a6fd-c091c8b474a1' User entered 'No (N)'	System	23 Aug 2020 20:10:16
	System	23 Aug 2020 20:10:16

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:09:59', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '227c3aae-fd8a-4d1f-a6fd-c091c8b474a1' User entered 'None (1)'	System	23 Aug 2020 20:10:16
	System	23 Aug 2020 20:10:16

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:10:10', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '227c3aae-fd8a-4d1f-a6fd-c091c8b474a1' User entered '23 Aug 2020 16:10'	System	23 Aug 2020 20:10:16
	System	23 Aug 2020 20:10:16

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 4'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:00:51', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b1d060a-c568-4ab1-8fb5-2ace0ab02f35'	System	25 Aug 2020 15:01:11
User entered 'None (1)'	System	25 Aug 2020 15:01:11

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:00:55', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b1d060a-c568-4ab1-8fb5-2ace0ab02f35'	System	25 Aug 2020 15:01:11
User entered 'No (N)'	System	25 Aug 2020 15:01:11

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:00:59', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b1d060a-c568-4ab1-8fb5-2ace0ab02f35'	System	25 Aug 2020 15:01:11
User entered 'No (N)'	System	25 Aug 2020 15:01:11

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:03', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b1d060a-c568-4ab1-8fb5-2ace0ab02f35'	System	25 Aug 2020 15:01:11
User entered 'None (1)'	System	25 Aug 2020 15:01:11

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:10', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b1d060a-c568-4ab1-8fb5-2ace0ab02f35' User entered '25 Aug 2020 11:01'	System	25 Aug 2020 15:01:11
	System	25 Aug 2020 15:01:11

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 5'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:09', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '25e3eca9-d9e2-46d8-9e44-2aa30d7a8c92'	System	26 Aug 2020 02:58:26
User entered 'None (1)'	System	26 Aug 2020 02:58:26

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:12', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '25e3eca9-d9e2-46d8-9e44-2aa30d7a8c92'	System	26 Aug 2020 02:58:26
User entered 'No (N)'	System	26 Aug 2020 02:58:26

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:15', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '25e3eca9-d9e2-46d8-9e44-2aa30d7a8c92'	System	26 Aug 2020 02:58:26
User entered 'No (N)'	System	26 Aug 2020 02:58:26

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:20', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '25e3eca9-d9e2-46d8-9e44-2aa30d7a8c92'	System	26 Aug 2020 02:58:26
User entered 'None (1)'	System	26 Aug 2020 02:58:26

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:25', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '25e3eca9-d9e2-46d8-9e44-2aa30d7a8c92'	System	26 Aug 2020 02:58:26
User entered '25 Aug 2020 22:58'	System	26 Aug 2020 02:58:26

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 6'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:24', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1a4f05c1-bacf-4b2f-809d-2b467db693b5'	System	26 Aug 2020 16:09:40
User entered 'None (1)'	System	26 Aug 2020 16:09:40

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:28', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1a4f05c1-bacf-4b2f-809d-2b467db693b5'	System	26 Aug 2020 16:09:40
User entered 'No (N)'	System	26 Aug 2020 16:09:40

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:31', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1a4f05c1-bacf-4b2f-809d-2b467db693b5' User entered 'No (N)'	System	26 Aug 2020 16:09:40
	System	26 Aug 2020 16:09:40

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:35', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1a4f05c1-bacf-4b2f-809d-2b467db693b5' User entered 'None (1)'	System	26 Aug 2020 16:09:40
	System	26 Aug 2020 16:09:40

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:39', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1a4f05c1-bacf-4b2f-809d-2b467db693b5' User entered '26 Aug 2020 12:09'	System	26 Aug 2020 16:09:40
	System	26 Aug 2020 16:09:40

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 7'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:15', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '738da660-f96e-4c93-bf5c-0f672a7d16f5'	System	27 Aug 2020 16:07:35
User entered 'None (1)'	System	27 Aug 2020 16:07:35

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:18', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '738da660-f96e-4c93-bf5c-0f672a7d16f5' User entered 'No (N)'	System	27 Aug 2020 16:07:35
	System	27 Aug 2020 16:07:35

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:22', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '738da660-f96e-4c93-bf5c-0f672a7d16f5'	System	27 Aug 2020 16:07:35
User entered 'No (N)'	System	27 Aug 2020 16:07:35

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:25', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '738da660-f96e-4c93-bf5c-0f672a7d16f5' User entered 'None (1)'	System	27 Aug 2020 16:07:35
	System	27 Aug 2020 16:07:35

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:30', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '738da660-f96e-4c93-bf5c-0f672a7d16f5' User entered '27 Aug 2020 12:07'	System	27 Aug 2020 16:07:35
	System	27 Aug 2020 16:07:35

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Aug 2020 10:23'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Aug 2020 12:53'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:29:14', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0969fd57-e601-4997-b1e3-f22e54a27181'	System	22 Aug 2020 00:30:05
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:30:05

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:29:09', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0969fd57-e601-4997-b1e3-f22e54a27181' User entered 'None (0)'	System	22 Aug 2020 00:30:05
	System	22 Aug 2020 00:30:05

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:28:57', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0969fd57-e601-4997-b1e3-f22e54a27181'	System	22 Aug 2020 00:30:05
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:30:05

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:28:51', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0969fd57-e601-4997-b1e3-f22e54a27181'	System	22 Aug 2020 00:30:05
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:30:05

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:28:40', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0969fd57-e601-4997-b1e3-f22e54a27181' User entered 'None (0)'	System	22 Aug 2020 00:30:05
	System	22 Aug 2020 00:30:05

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:29:24', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0969fd57-e601-4997-b1e3-f22e54a27181' User entered 'None (0)'	System	22 Aug 2020 00:30:05
	System	22 Aug 2020 00:30:05

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:29:39', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0969fd57-e601-4997-b1e3-f22e54a27181' User entered 'No (N)'	System	22 Aug 2020 00:30:05
	System	22 Aug 2020 00:30:05

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-21T20:30:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0969fd57-e601-4997-b1e3-f22e54a27181'	System	22 Aug 2020 00:30:05
User entered '21 Aug 2020 20:30'	System	22 Aug 2020 00:30:05

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Aug 2020 13:48'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 2'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:54:33', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd3c0e842-2d09-4691-9216-25743cc9bf24'	System	22 Aug 2020 22:55:25
User entered 'No interference with activity (1)'	System	22 Aug 2020 22:55:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:54:46', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd3c0e842-2d09-4691-9216-25743cc9bf24'	System	22 Aug 2020 22:55:25
User entered 'No interference with activity (1)'	System	22 Aug 2020 22:55:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:54:57', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd3c0e842-2d09-4691-9216-25743cc9bf24'	System	22 Aug 2020 22:55:25
User entered 'No interference with activity (1)'	System	22 Aug 2020 22:55:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:55:01', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd3c0e842-2d09-4691-9216-25743cc9bf24' User entered 'None (0)'	System	22 Aug 2020 22:55:25
	System	22 Aug 2020 22:55:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:55:05', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd3c0e842-2d09-4691-9216-25743cc9bf24' User entered 'None (0)'	System	22 Aug 2020 22:55:25
	System	22 Aug 2020 22:55:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:55:08', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd3c0e842-2d09-4691-9216-25743cc9bf24' User entered 'None (0)'	System	22 Aug 2020 22:55:25
	System	22 Aug 2020 22:55:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:55:13', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd3c0e842-2d09-4691-9216-25743cc9bf24'	System	22 Aug 2020 22:55:25
User entered 'No (N)'	System	22 Aug 2020 22:55:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-22T18:55:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd3c0e842-2d09-4691-9216-25743cc9bf24'	System	22 Aug 2020 22:55:25
User entered '22 Aug 2020 18:55'	System	22 Aug 2020 22:55:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 3'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:10:17', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7820fde4-9d04-42e5-b1f2-11c9d162d276' User entered 'None (0)'	System	23 Aug 2020 20:10:54
	System	23 Aug 2020 20:10:54

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:10:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7820fde4-9d04-42e5-b1f2-11c9d162d276'	System	23 Aug 2020 20:10:54
User entered 'No interference with activity (1)'	System	23 Aug 2020 20:10:54

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:10:26', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7820fde4-9d04-42e5-b1f2-11c9d162d276' User entered 'None (0)'	System	23 Aug 2020 20:10:54
	System	23 Aug 2020 20:10:54

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:10:31', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7820fde4-9d04-42e5-b1f2-11c9d162d276' User entered 'None (0)'	System	23 Aug 2020 20:10:54
	System	23 Aug 2020 20:10:54

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:10:34', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7820fde4-9d04-42e5-b1f2-11c9d162d276' User entered 'None (0)'	System	23 Aug 2020 20:10:54
	System	23 Aug 2020 20:10:54

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:10:38', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7820fde4-9d04-42e5-b1f2-11c9d162d276' User entered 'None (0)'	System	23 Aug 2020 20:10:54
	System	23 Aug 2020 20:10:54

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:10:43', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7820fde4-9d04-42e5-b1f2-11c9d162d276'	System	23 Aug 2020 20:10:54
User entered 'No (N)'	System	23 Aug 2020 20:10:54

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-23T16:10:52', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7820fde4-9d04-42e5-b1f2-11c9d162d276' User entered '23 Aug 2020 16:10'	System	23 Aug 2020 20:10:54
	System	23 Aug 2020 20:10:54

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 4'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:14', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1cfac5db-951a-4af9-b9f8-a692dcd632a6' User entered 'None (0)'	System	25 Aug 2020 15:01:43
	System	25 Aug 2020 15:01:43

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:18', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1cfac5db-951a-4af9-b9f8-a692dcd632a6' User entered 'None (0)'	System	25 Aug 2020 15:01:43
	System	25 Aug 2020 15:01:43

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:21', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1cfac5db-951a-4af9-b9f8-a692dcd632a6' User entered 'None (0)'	System	25 Aug 2020 15:01:43
	System	25 Aug 2020 15:01:43

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:26', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1cfac5db-951a-4af9-b9f8-a692dcd632a6' User entered 'None (0)'	System	25 Aug 2020 15:01:43
	System	25 Aug 2020 15:01:43

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:29', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1cfac5db-951a-4af9-b9f8-a692dcd632a6' User entered 'None (0)'	System	25 Aug 2020 15:01:43
	System	25 Aug 2020 15:01:43

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:32', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1cfac5db-951a-4af9-b9f8-a692dcd632a6' User entered 'None (0)'	System	25 Aug 2020 15:01:43
	System	25 Aug 2020 15:01:43

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:36', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1cfac5db-951a-4af9-b9f8-a692dcd632a6' User entered 'No (N)'	System	25 Aug 2020 15:01:43
	System	25 Aug 2020 15:01:43

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T11:01:42', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1cfac5db-951a-4af9-b9f8-a692dcd632a6' User entered '25 Aug 2020 11:01'	System	25 Aug 2020 15:01:43
	System	25 Aug 2020 15:01:43

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 5'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:30', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5adba0a1-4617-4ed0-b5a6-d0d22d6c144f' User entered 'None (0)'	System	26 Aug 2020 02:58:59
	System	26 Aug 2020 02:58:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:33', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5adba0a1-4617-4ed0-b5a6-d0d22d6c144f' User entered 'None (0)'	System	26 Aug 2020 02:58:59
	System	26 Aug 2020 02:58:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:36', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5adba0a1-4617-4ed0-b5a6-d0d22d6c144f' User entered 'None (0)'	System	26 Aug 2020 02:58:59
	System	26 Aug 2020 02:58:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:40', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5adba0a1-4617-4ed0-b5a6-d0d22d6c144f' User entered 'None (0)'	System	26 Aug 2020 02:58:59
	System	26 Aug 2020 02:58:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:44', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5adba0a1-4617-4ed0-b5a6-d0d22d6c144f' User entered 'None (0)'	System	26 Aug 2020 02:58:59
	System	26 Aug 2020 02:58:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:47', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5adba0a1-4617-4ed0-b5a6-d0d22d6c144f' User entered 'None (0)'	System	26 Aug 2020 02:58:59
	System	26 Aug 2020 02:58:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:53', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5adba0a1-4617-4ed0-b5a6-d0d22d6c144f' User entered 'No (N)'	System	26 Aug 2020 02:58:59
	System	26 Aug 2020 02:58:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-25T22:58:57', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5adba0a1-4617-4ed0-b5a6-d0d22d6c144f' User entered '25 Aug 2020 22:58'	System	26 Aug 2020 02:58:59
	System	26 Aug 2020 02:58:59

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 6'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:44', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c77665ea-7548-45c0-b1c7-279e7aac0978' User entered 'None (0)'	System	26 Aug 2020 16:10:15
	System	26 Aug 2020 16:10:15

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:48', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c77665ea-7548-45c0-b1c7-279e7aac0978' User entered 'None (0)'	System	26 Aug 2020 16:10:15
	System	26 Aug 2020 16:10:15

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:51', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c77665ea-7548-45c0-b1c7-279e7aac0978' User entered 'None (0)'	System	26 Aug 2020 16:10:15
	System	26 Aug 2020 16:10:15

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:54', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c77665ea-7548-45c0-b1c7-279e7aac0978' User entered 'None (0)'	System	26 Aug 2020 16:10:15
	System	26 Aug 2020 16:10:15

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:09:56', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c77665ea-7548-45c0-b1c7-279e7aac0978' User entered 'None (0)'	System	26 Aug 2020 16:10:15
	System	26 Aug 2020 16:10:15

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:10:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c77665ea-7548-45c0-b1c7-279e7aac0978' User entered 'None (0)'	System	26 Aug 2020 16:10:15
	System	26 Aug 2020 16:10:15

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:10:04', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c77665ea-7548-45c0-b1c7-279e7aac0978' User entered 'No (N)'	System	26 Aug 2020 16:10:15
	System	26 Aug 2020 16:10:15

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-26T12:10:13', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c77665ea-7548-45c0-b1c7-279e7aac0978' User entered '26 Aug 2020 12:10'	System	26 Aug 2020 16:10:15
	System	26 Aug 2020 16:10:15

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 7'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:35', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b13c45e-505c-4d3e-84b2-7f559a29a99e' User entered 'None (0)'	System	27 Aug 2020 16:08:11
	System	27 Aug 2020 16:08:11

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:38', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b13c45e-505c-4d3e-84b2-7f559a29a99e' User entered 'None (0)'	System	27 Aug 2020 16:08:11
	System	27 Aug 2020 16:08:11

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:41', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b13c45e-505c-4d3e-84b2-7f559a29a99e' User entered 'None (0)'	System	27 Aug 2020 16:08:11
	System	27 Aug 2020 16:08:11

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:44', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b13c45e-505c-4d3e-84b2-7f559a29a99e' User entered 'None (0)'	System	27 Aug 2020 16:08:11
	System	27 Aug 2020 16:08:11

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:47', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b13c45e-505c-4d3e-84b2-7f559a29a99e' User entered 'None (0)'	System	27 Aug 2020 16:08:11
	System	27 Aug 2020 16:08:11

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:49', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b13c45e-505c-4d3e-84b2-7f559a29a99e' User entered 'None (0)'	System	27 Aug 2020 16:08:11
	System	27 Aug 2020 16:08:11

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:07:53', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b13c45e-505c-4d3e-84b2-7f559a29a99e' User entered 'No (N)'	System	27 Aug 2020 16:08:11
	System	27 Aug 2020 16:08:11

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-08-27T12:08:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0b13c45e-505c-4d3e-84b2-7f559a29a99e' User entered '27 Aug 2020 12:08'	System	27 Aug 2020 16:08:11
	System	27 Aug 2020 16:08:11

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 14:10:25

US3082081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	04 Sep 2020 12:28:51

US3082081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '28 Aug 2020'	Alice Cipollini (b) (4)	04 Sep 2020 12:28:51

US3082081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Contact Made (CONTACT MADE)'	Alice Cipollini (b) (4)	04 Sep 2020 12:28:51

US3082081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	04 Sep 2020 12:28:51

US3082081

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	04 Sep 2020 12:28:57

US3082081

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	04 Sep 2020 12:28:57

US3082081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	04 Sep 2020 12:44:01

US3082081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '4 Sep 2020'	Alice Cipollini (b) (4)	04 Sep 2020 12:44:01

US3082081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Contact Made (CONTACT MADE)'	Alice Cipollini (b) (4)	04 Sep 2020 12:44:01

US3082081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Alice Cipollini (b) (4)	04 Sep 2020 12:44:01

US3082081

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Alice Cipollini (b) (4)	04 Sep 2020 12:44:09

US3082081

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	04 Sep 2020 12:44:09

US3082081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Ayssa Valente (b) (4)	11 Sep 2020 13:11:50

US3082081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '11 Sep 2020'	Ayssa Valente (b) (4)	11 Sep 2020 13:11:50

US3082081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Contact Made (CONTACT MADE)'	Ayssa Valente (b) (4)	11 Sep 2020 13:11:50

US3082081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	(b) (4) Ayssa Valente (b) (4)	11 Sep 2020 13:11:50

US3082081

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Ayssa Valente (b) (4)	11 Sep 2020 13:11:55

US3082081

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	11 Sep 2020 13:11:55

US3082081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:28:07

US3082081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Sep 2020'	Ayssa Valente (b) (4)	21 Sep 2020 14:28:07

US3082081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Clinic (Clinic)'	Ayssa Valente (b) (4)	21 Sep 2020 14:28:07

US3082081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'VISIT2'	System	21 Sep 2020 14:28:07

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User accepted default value 'Pre-Dose (PREDOSE)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Sep 2020'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '09:53'	Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Sep 2020 09:53'	System	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '97.7' F	Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Oral (Oral)'	Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '69'	Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'bpm'	System	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '16'	Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'breaths/min'	System	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '115'	Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '70'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	21 Sep 2020 14:29:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User accepted default value 'Post-Dose (POSTDOSE)'	Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Sep 2020'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '11:08'	Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Sep 2020 11:08'	System	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '97.8' F	Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Oral (Oral)'	Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '73'	Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'bpm'	System	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '16'	Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'breaths/min'	System	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '104'	Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '65'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	21 Sep 2020 15:20:02

US3082081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	21 Sep 2020 14:30:54

US3082081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Sep 2020'	Ayssa Valente (b) (4)	21 Sep 2020 14:30:54

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Sep 2020'	Ayssa Valente (b) (4)	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '10:37'	Ayssa Valente (b) (4)	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Sep 2020 10:37'	System	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Left Arm (LEFT ARM)'	Ayssa Valente (b) (4)	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'ONCE'	System	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 14:50:49

US3082081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	21 Sep 2020 14:31:15

US3082081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Sep 2020'	Ayssa Valente (b) (4)	21 Sep 2020 14:31:15

US3082081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '10:19'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:31:15

US3082081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Sep 2020 10:19'	System	21 Sep 2020 14:31:15

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:03:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '21 Sep 2020'	Ayssa Valente (b) (4)	21 Sep 2020 14:31:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:31:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Ayssa Valente (b) (4)	21 Sep 2020 14:31:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '10:22'	Ayssa Valente (b) (4)	21 Sep 2020 14:31:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '21 Sep 2020 10:22'	System	21 Sep 2020 14:31:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:31:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'No (N)'	Ayssa Valente (b) (4)	21 Sep 2020 14:31:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Ayssa Valente (b) (4)	21 Sep 2020 14:31:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered empty.	System	21 Sep 2020 14:31:29

US3082081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	21 Sep 2020 14:31:34

US3082081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	21 Sep 2020 14:31:34

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:02', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'dc639b08-cf87-4338-b4a4-e2f3a4875199'	System	21 Sep 2020 15:10:25
User entered 'Yes (Y)'	System	21 Sep 2020 15:10:25

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:11', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'dc639b08-cf87-4338-b4a4-e2f3a4875199' User entered '97.8'	System	21 Sep 2020 15:10:25
	System	21 Sep 2020 15:10:25

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:15', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'dc639b08-cf87-4338-b4a4-e2f3a4875199'	System	21 Sep 2020 15:10:25
User entered 'No (N)'	System	21 Sep 2020 15:10:25

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:21', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'dc639b08-cf87-4338-b4a4-e2f3a4875199'	System	21 Sep 2020 15:10:25
User entered '21 Sep 2020 11:10'	System	21 Sep 2020 15:10:25

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Sep 2020 10:57'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Sep 2020 13:27'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:15:33', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2633dbc8-881a-47e1-9bc1-fd6e0ebdc9c5' User entered 'Yes (Y)'	System	22 Sep 2020 11:15:56
	System	22 Sep 2020 11:15:56

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:15:43', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2633dbc8-881a-47e1-9bc1-fd6e0ebdc9c5' User entered '97.8'	System	22 Sep 2020 11:15:56
	System	22 Sep 2020 11:15:56

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:15:48', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2633dbc8-881a-47e1-9bc1-fd6e0ebdc9c5'	System	22 Sep 2020 11:15:56
User entered 'No (N)'	System	22 Sep 2020 11:15:56

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:15:55', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2633dbc8-881a-47e1-9bc1-fd6e0ebdc9c5' User entered '22 Sep 2020 07:15'	System	22 Sep 2020 11:15:56
	System	22 Sep 2020 11:15:56

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Sep 2020 14:22'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 2'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:32:36', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00c4b1f1-0044-4001-a57f-58ce31d131df' User entered 'Yes (Y)'	System	22 Sep 2020 23:32:54
	System	22 Sep 2020 23:32:54

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:32:42', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00c4b1f1-0044-4001-a57f-58ce31d131df' User entered '98.2'	System	22 Sep 2020 23:32:54
	System	22 Sep 2020 23:32:54

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:32:46', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00c4b1f1-0044-4001-a57f-58ce31d131df'	System	22 Sep 2020 23:32:54
User entered 'No (N)'	System	22 Sep 2020 23:32:54

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:32:50', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00c4b1f1-0044-4001-a57f-58ce31d131df' User entered '22 Sep 2020 19:32'	System	22 Sep 2020 23:32:54
	System	22 Sep 2020 23:32:54

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 3'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:32:39', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ae6a1991-4afd-49cb-8354-2cf8df4dbc62'	System	23 Sep 2020 21:32:57
User entered 'Yes (Y)'	System	23 Sep 2020 21:32:57

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:32:45', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ae6a1991-4afd-49cb-8354-2cf8df4dbc62' User entered '98.2'	System	23 Sep 2020 21:32:57
	System	23 Sep 2020 21:32:57

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:32:49', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ae6a1991-4afd-49cb-8354-2cf8df4dbc62'	System	23 Sep 2020 21:32:57
User entered 'No (N)'	System	23 Sep 2020 21:32:57

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:32:54', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ae6a1991-4afd-49cb-8354-2cf8df4dbc62'	System	23 Sep 2020 21:32:57
User entered '23 Sep 2020 17:32'	System	23 Sep 2020 21:32:57

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 4'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:43:50', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '37a8be00-ed03-4076-bbb5-19906aa3b107' User entered 'Yes (Y)'	System	24 Sep 2020 17:44:11
	System	24 Sep 2020 17:44:11

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:43:55', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '37a8be00-ed03-4076-bbb5-19906aa3b107' User entered '97.7'	System	24 Sep 2020 17:44:11
	System	24 Sep 2020 17:44:11

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:43:59', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '37a8be00-ed03-4076-bbb5-19906aa3b107'	System	24 Sep 2020 17:44:11
User entered 'No (N)'	System	24 Sep 2020 17:44:11

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:44:03', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '37a8be00-ed03-4076-bbb5-19906aa3b107'	System	24 Sep 2020 17:44:11
User entered '24 Sep 2020 13:44'	System	24 Sep 2020 17:44:11

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 5'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:19:53', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '94fddfd6-cddb-4415-a174-344017096666'	System	25 Sep 2020 20:20:11
User entered 'Yes (Y)'	System	25 Sep 2020 20:20:11

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:01', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '94fddfd6-cddb-4415-a174-344017096666' User entered '98.2'	System	25 Sep 2020 20:20:11
	System	25 Sep 2020 20:20:11

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:04', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '94fddfd6-cddb-4415-a174-344017096666'	System	25 Sep 2020 20:20:11
User entered 'No (N)'	System	25 Sep 2020 20:20:11

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:09', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '94fddfd6-cddb-4415-a174-344017096666'	System	25 Sep 2020 20:20:11
User entered '25 Sep 2020 16:20'	System	25 Sep 2020 20:20:11

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 6'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:33:20', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ac98d0f1-a7da-42dd-a16e-4b5cbd5fc9f0'	System	27 Sep 2020 00:33:41
User entered 'Yes (Y)'	System	27 Sep 2020 00:33:41

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:33:30', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ac98d0f1-a7da-42dd-a16e-4b5cbd5fc9f0' User entered '98.0'	System	27 Sep 2020 00:33:41
	System	27 Sep 2020 00:33:41

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:33:33', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ac98d0f1-a7da-42dd-a16e-4b5cbd5fc9f0'	System	27 Sep 2020 00:33:41
User entered 'No (N)'	System	27 Sep 2020 00:33:41

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:33:39', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ac98d0f1-a7da-42dd-a16e-4b5cbd5fc9f0' User entered '26 Sep 2020 20:33'	System	27 Sep 2020 00:33:41
	System	27 Sep 2020 00:33:41

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 7'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:20:37', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '883a4230-82ed-41e3-aa1c-ba1d7b29db18' User entered 'Yes (Y)'	System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:20:42', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '883a4230-82ed-41e3-aa1c-ba1d7b29db18' User entered '98.2'	System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:20:46', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '883a4230-82ed-41e3-aa1c-ba1d7b29db18'	System	27 Sep 2020 16:20:54
User entered 'No (N)'	System	27 Sep 2020 16:20:54

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:20:50', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '883a4230-82ed-41e3-aa1c-ba1d7b29db18' User entered '27 Sep 2020 12:20'	System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:32', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1d79d686-23a6-4fd2-8de4-f606eede2a03'	System	21 Sep 2020 15:10:58
User entered 'None (1)'	System	21 Sep 2020 15:10:58

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:36', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1d79d686-23a6-4fd2-8de4-f606eede2a03' User entered 'No (N)'	System	21 Sep 2020 15:10:58
	System	21 Sep 2020 15:10:58

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:43', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1d79d686-23a6-4fd2-8de4-f606eede2a03' User entered 'No (N)'	System	21 Sep 2020 15:10:58
	System	21 Sep 2020 15:10:58

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:47', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1d79d686-23a6-4fd2-8de4-f606eede2a03'	System	21 Sep 2020 15:10:58
User entered 'None (1)'	System	21 Sep 2020 15:10:58

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:52', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1d79d686-23a6-4fd2-8de4-f606eede2a03'	System	21 Sep 2020 15:10:58
User entered '21 Sep 2020 11:10'	System	21 Sep 2020 15:10:58

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Sep 2020 10:57'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Sep 2020 13:27'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:16:14', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00550b20-7875-4a23-aa20-d4f19f4beaa7'	System	22 Sep 2020 11:17:43
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 11:17:43

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:16:18', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00550b20-7875-4a23-aa20-d4f19f4beaa7' User entered 'No (N)'	System	22 Sep 2020 11:17:43
	System	22 Sep 2020 11:17:43

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:16:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00550b20-7875-4a23-aa20-d4f19f4beaa7'	System	22 Sep 2020 11:17:43
User entered 'Yes (Y)'	System	22 Sep 2020 11:17:43

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:17:26', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00550b20-7875-4a23-aa20-d4f19f4beaa7' User entered '6'	System	22 Sep 2020 11:17:43
	System	22 Sep 2020 11:17:43

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:17:30', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00550b20-7875-4a23-aa20-d4f19f4beaa7'	System	22 Sep 2020 11:17:43
User entered 'None (1)'	System	22 Sep 2020 11:17:43

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:17:38', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '00550b20-7875-4a23-aa20-d4f19f4beaa7' User entered '22 Sep 2020 07:17'	System	22 Sep 2020 11:17:43
	System	22 Sep 2020 11:17:43

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Sep 2020 14:22'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 2'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:32:59', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f087dda7-0375-49c7-93a1-e71597cf8058'	System	22 Sep 2020 23:33:32
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 23:33:32

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:33:02', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f087dda7-0375-49c7-93a1-e71597cf8058'	System	22 Sep 2020 23:33:32
User entered 'No (N)'	System	22 Sep 2020 23:33:32

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:33:06', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f087dda7-0375-49c7-93a1-e71597cf8058'	System	22 Sep 2020 23:33:32
User entered 'Yes (Y)'	System	22 Sep 2020 23:33:32

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:33:17', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f087dda7-0375-49c7-93a1-e71597cf8058' User entered '6'	System	22 Sep 2020 23:33:32
	System	22 Sep 2020 23:33:32

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:33:21', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f087dda7-0375-49c7-93a1-e71597cf8058'	System	22 Sep 2020 23:33:32
User entered 'None (1)'	System	22 Sep 2020 23:33:32

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:33:28', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f087dda7-0375-49c7-93a1-e71597cf8058' User entered '22 Sep 2020 19:33'	System	22 Sep 2020 23:33:32
	System	22 Sep 2020 23:33:32

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 3'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'acdf5de3-0081-4557-819f-0973b99228af'	System	23 Sep 2020 21:33:36
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 21:33:36

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:04', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'acdf5de3-0081-4557-819f-0973b99228af' User entered 'No (N)'	System	23 Sep 2020 21:33:36
	System	23 Sep 2020 21:33:36

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:09', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'acdf5de3-0081-4557-819f-0973b99228af' User entered 'Yes (Y)'	System	23 Sep 2020 21:33:36
	System	23 Sep 2020 21:33:36

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:19', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'acdf5de3-0081-4557-819f-0973b99228af' User entered '4'	System	23 Sep 2020 21:33:36
	System	23 Sep 2020 21:33:36

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'acdf5de3-0081-4557-819f-0973b99228af' User entered 'None (1)'	System	23 Sep 2020 21:33:36
	System	23 Sep 2020 21:33:36

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:33', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'acdf5de3-0081-4557-819f-0973b99228af' User entered '23 Sep 2020 17:33'	System	23 Sep 2020 21:33:36
	System	23 Sep 2020 21:33:36

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 4'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:44:18', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'bdf13296-e208-42e9-a7e3-d317680937ab'	System	24 Sep 2020 17:44:46
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 17:44:46

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:44:21', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'bdf13296-e208-42e9-a7e3-d317680937ab' User entered 'No (N)'	System	24 Sep 2020 17:44:46
	System	24 Sep 2020 17:44:46

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:44:25', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'bdf13296-e208-42e9-a7e3-d317680937ab' User entered 'Yes (Y)'	System	24 Sep 2020 17:44:46
	System	24 Sep 2020 17:44:46

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:44:31', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'bdf13296-e208-42e9-a7e3-d317680937ab' User entered '3'	System	24 Sep 2020 17:44:46
	System	24 Sep 2020 17:44:46

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:44:37', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'bdf13296-e208-42e9-a7e3-d317680937ab' User entered 'None (1)'	System	24 Sep 2020 17:44:46
	System	24 Sep 2020 17:44:46

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:44:44', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'bdf13296-e208-42e9-a7e3-d317680937ab' User entered '24 Sep 2020 13:44'	System	24 Sep 2020 17:44:46
	System	24 Sep 2020 17:44:46

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 5'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:20', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9033e3af-1093-49b5-b7d9-39cb1436dce7'	System	25 Sep 2020 20:20:45
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 20:20:45

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9033e3af-1093-49b5-b7d9-39cb1436dce7'	System	25 Sep 2020 20:20:45
User entered 'No (N)'	System	25 Sep 2020 20:20:45

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:29', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9033e3af-1093-49b5-b7d9-39cb1436dce7'	System	25 Sep 2020 20:20:45
User entered 'Yes (Y)'	System	25 Sep 2020 20:20:45

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:34', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9033e3af-1093-49b5-b7d9-39cb1436dce7' User entered '2'	System	25 Sep 2020 20:20:45
	System	25 Sep 2020 20:20:45

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:37', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9033e3af-1093-49b5-b7d9-39cb1436dce7'	System	25 Sep 2020 20:20:45
User entered 'None (1)'	System	25 Sep 2020 20:20:45

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:43', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9033e3af-1093-49b5-b7d9-39cb1436dce7'	System	25 Sep 2020 20:20:45
User entered '25 Sep 2020 16:20'	System	25 Sep 2020 20:20:45

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 6'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:33:54', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c75805a6-75db-45d9-b513-61db62aab20b'	System	27 Sep 2020 00:34:10
User entered 'None (1)'	System	27 Sep 2020 00:34:10

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:33:57', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c75805a6-75db-45d9-b513-61db62aab20b'	System	27 Sep 2020 00:34:10
User entered 'No (N)'	System	27 Sep 2020 00:34:10

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c75805a6-75db-45d9-b513-61db62aab20b'	System	27 Sep 2020 00:34:10
User entered 'No (N)'	System	27 Sep 2020 00:34:10

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:03', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c75805a6-75db-45d9-b513-61db62aab20b'	System	27 Sep 2020 00:34:10
User entered 'None (1)'	System	27 Sep 2020 00:34:10

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:08', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c75805a6-75db-45d9-b513-61db62aab20b' User entered '26 Sep 2020 20:34'	System	27 Sep 2020 00:34:10
	System	27 Sep 2020 00:34:10

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 7'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f16f213a-d7ca-4447-9d25-cddae263e841'	System	27 Sep 2020 16:21:17
User entered 'None (1)'	System	27 Sep 2020 16:21:17

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:03', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f16f213a-d7ca-4447-9d25-cddae263e841' User entered 'No (N)'	System	27 Sep 2020 16:21:17
	System	27 Sep 2020 16:21:17

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:06', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f16f213a-d7ca-4447-9d25-cddae263e841' User entered 'No (N)'	System	27 Sep 2020 16:21:17
	System	27 Sep 2020 16:21:17

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:09', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f16f213a-d7ca-4447-9d25-cddae263e841'	System	27 Sep 2020 16:21:17
User entered 'None (1)'	System	27 Sep 2020 16:21:17

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:15', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f16f213a-d7ca-4447-9d25-cddae263e841' User entered '27 Sep 2020 12:21'	System	27 Sep 2020 16:21:17
	System	27 Sep 2020 16:21:17

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:10:58', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9d0efe3c-7b56-4a8f-9f12-c12fcd095011' User entered 'None (0)'	System	21 Sep 2020 15:11:39
	System	21 Sep 2020 15:11:39

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:11:02', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9d0efe3c-7b56-4a8f-9f12-c12fcd095011' User entered 'None (0)'	System	21 Sep 2020 15:11:39
	System	21 Sep 2020 15:11:39

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:11:11', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9d0efe3c-7b56-4a8f-9f12-c12fcd095011' User entered 'None (0)'	System	21 Sep 2020 15:11:39
	System	21 Sep 2020 15:11:39

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:11:13', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9d0efe3c-7b56-4a8f-9f12-c12fcd095011' User entered 'None (0)'	System	21 Sep 2020 15:11:39
	System	21 Sep 2020 15:11:39

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:11:21', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9d0efe3c-7b56-4a8f-9f12-c12fcd095011' User entered 'None (0)'	System	21 Sep 2020 15:11:39
	System	21 Sep 2020 15:11:39

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:11:24', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9d0efe3c-7b56-4a8f-9f12-c12fcd095011' User entered 'None (0)'	System	21 Sep 2020 15:11:39
	System	21 Sep 2020 15:11:39

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:11:31', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9d0efe3c-7b56-4a8f-9f12-c12fcd095011' User entered 'No (N)'	System	21 Sep 2020 15:11:39
	System	21 Sep 2020 15:11:39

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-21T11:11:37', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '9d0efe3c-7b56-4a8f-9f12-c12fcd095011' User entered '21 Sep 2020 11:11'	System	21 Sep 2020 15:11:39
	System	21 Sep 2020 15:11:39

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Sep 2020 10:57'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Sep 2020 13:27'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:17:43', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1b968558-8530-45ec-b601-d5953e3f2070' User entered 'None (0)'	System	22 Sep 2020 11:18:24
	System	22 Sep 2020 11:18:24

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:17:46', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1b968558-8530-45ec-b601-d5953e3f2070' User entered 'None (0)'	System	22 Sep 2020 11:18:24
	System	22 Sep 2020 11:18:24

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:17:50', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1b968558-8530-45ec-b601-d5953e3f2070' User entered 'None (0)'	System	22 Sep 2020 11:18:24
	System	22 Sep 2020 11:18:24

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:17:54', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1b968558-8530-45ec-b601-d5953e3f2070' User entered 'None (0)'	System	22 Sep 2020 11:18:24
	System	22 Sep 2020 11:18:24

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:17:57', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1b968558-8530-45ec-b601-d5953e3f2070' User entered 'None (0)'	System	22 Sep 2020 11:18:24
	System	22 Sep 2020 11:18:24

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:18:10', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1b968558-8530-45ec-b601-d5953e3f2070' User entered 'None (0)'	System	22 Sep 2020 11:18:24
	System	22 Sep 2020 11:18:24

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:18:15', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1b968558-8530-45ec-b601-d5953e3f2070' User entered 'No (N)'	System	22 Sep 2020 11:18:24
	System	22 Sep 2020 11:18:24

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T07:18:20', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '1b968558-8530-45ec-b601-d5953e3f2070' User entered '22 Sep 2020 07:18'	System	22 Sep 2020 11:18:24
	System	22 Sep 2020 11:18:24

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '21 Sep 2020 14:22'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 2'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:33:36', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4fcc7d5c-6ae0-4ca4-af3d-950aea0fb138'	System	22 Sep 2020 23:34:18
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:34:18

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:33:42', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4fcc7d5c-6ae0-4ca4-af3d-950aea0fb138'	System	22 Sep 2020 23:34:18
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:34:18

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:33:48', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4fcc7d5c-6ae0-4ca4-af3d-950aea0fb138'	System	22 Sep 2020 23:34:18
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:34:18

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:33:54', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4fcc7d5c-6ae0-4ca4-af3d-950aea0fb138' User entered 'None (0)'	System	22 Sep 2020 23:34:18
	System	22 Sep 2020 23:34:18

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:34:02', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4fcc7d5c-6ae0-4ca4-af3d-950aea0fb138' User entered 'None (0)'	System	22 Sep 2020 23:34:18
	System	22 Sep 2020 23:34:18

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:34:06', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4fcc7d5c-6ae0-4ca4-af3d-950aea0fb138'	System	22 Sep 2020 23:34:18
User entered 'None (0)'	System	22 Sep 2020 23:34:18

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:34:10', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4fcc7d5c-6ae0-4ca4-af3d-950aea0fb138'	System	22 Sep 2020 23:34:18
User entered 'No (N)'	System	22 Sep 2020 23:34:18

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-22T19:34:17', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4fcc7d5c-6ae0-4ca4-af3d-950aea0fb138' User entered '22 Sep 2020 19:34'	System	22 Sep 2020 23:34:18
	System	22 Sep 2020 23:34:18

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 3'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:38', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5f2fa73c-95d5-42d9-930d-122a69861e91' User entered 'None (0)'	System	23 Sep 2020 21:34:09
	System	23 Sep 2020 21:34:09

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:41', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5f2fa73c-95d5-42d9-930d-122a69861e91' User entered 'None (0)'	System	23 Sep 2020 21:34:09
	System	23 Sep 2020 21:34:09

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:44', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5f2fa73c-95d5-42d9-930d-122a69861e91' User entered 'None (0)'	System	23 Sep 2020 21:34:09
	System	23 Sep 2020 21:34:09

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:47', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5f2fa73c-95d5-42d9-930d-122a69861e91' User entered 'None (0)'	System	23 Sep 2020 21:34:09
	System	23 Sep 2020 21:34:09

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:50', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5f2fa73c-95d5-42d9-930d-122a69861e91' User entered 'None (0)'	System	23 Sep 2020 21:34:09
	System	23 Sep 2020 21:34:09

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:55', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5f2fa73c-95d5-42d9-930d-122a69861e91' User entered 'None (0)'	System	23 Sep 2020 21:34:09
	System	23 Sep 2020 21:34:09

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:33:59', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5f2fa73c-95d5-42d9-930d-122a69861e91' User entered 'No (N)'	System	23 Sep 2020 21:34:09
	System	23 Sep 2020 21:34:09

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-23T17:34:05', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5f2fa73c-95d5-42d9-930d-122a69861e91' User entered '23 Sep 2020 17:34'	System	23 Sep 2020 21:34:09
	System	23 Sep 2020 21:34:09

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 4'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:44:50', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0867b053-c020-48cd-8c51-d66910d526f6' User entered 'None (0)'	System	24 Sep 2020 17:45:22
	System	24 Sep 2020 17:45:22

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:44:58', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0867b053-c020-48cd-8c51-d66910d526f6'	System	24 Sep 2020 17:45:22
User entered 'No interference with activity (1)'	System	24 Sep 2020 17:45:22

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:45:01', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0867b053-c020-48cd-8c51-d66910d526f6' User entered 'None (0)'	System	24 Sep 2020 17:45:22
	System	24 Sep 2020 17:45:22

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:45:04', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0867b053-c020-48cd-8c51-d66910d526f6' User entered 'None (0)'	System	24 Sep 2020 17:45:22
	System	24 Sep 2020 17:45:22

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:45:07', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0867b053-c020-48cd-8c51-d66910d526f6' User entered 'None (0)'	System	24 Sep 2020 17:45:22
	System	24 Sep 2020 17:45:22

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:45:10', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0867b053-c020-48cd-8c51-d66910d526f6' User entered 'None (0)'	System	24 Sep 2020 17:45:22
	System	24 Sep 2020 17:45:22

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:45:16', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0867b053-c020-48cd-8c51-d66910d526f6' User entered 'No (N)'	System	24 Sep 2020 17:45:22
	System	24 Sep 2020 17:45:22

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-24T13:45:20', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0867b053-c020-48cd-8c51-d66910d526f6' User entered '24 Sep 2020 13:45'	System	24 Sep 2020 17:45:22
	System	24 Sep 2020 17:45:22

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 5'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:48', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '066ee6b6-e5dc-4c06-8433-d2b7baa69967' User entered 'None (0)'	System	25 Sep 2020 20:21:12
	System	25 Sep 2020 20:21:12

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:51', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '066ee6b6-e5dc-4c06-8433-d2b7baa69967' User entered 'None (0)'	System	25 Sep 2020 20:21:12
	System	25 Sep 2020 20:21:12

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:53', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '066ee6b6-e5dc-4c06-8433-d2b7baa69967' User entered 'None (0)'	System	25 Sep 2020 20:21:12
	System	25 Sep 2020 20:21:12

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:56', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '066ee6b6-e5dc-4c06-8433-d2b7baa69967' User entered 'None (0)'	System	25 Sep 2020 20:21:12
	System	25 Sep 2020 20:21:12

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:20:59', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '066ee6b6-e5dc-4c06-8433-d2b7baa69967' User entered 'None (0)'	System	25 Sep 2020 20:21:12
	System	25 Sep 2020 20:21:12

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:21:02', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '066ee6b6-e5dc-4c06-8433-d2b7baa69967' User entered 'None (0)'	System	25 Sep 2020 20:21:12
	System	25 Sep 2020 20:21:12

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:21:05', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '066ee6b6-e5dc-4c06-8433-d2b7baa69967' User entered 'No (N)'	System	25 Sep 2020 20:21:12
	System	25 Sep 2020 20:21:12

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-25T16:21:10', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '066ee6b6-e5dc-4c06-8433-d2b7baa69967' User entered '25 Sep 2020 16:21'	System	25 Sep 2020 20:21:12
	System	25 Sep 2020 20:21:12

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 6'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:13', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ab1b8567-f524-48bd-b708-768e1e4d2f11' User entered 'None (0)'	System	27 Sep 2020 00:34:42
	System	27 Sep 2020 00:34:42

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:17', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ab1b8567-f524-48bd-b708-768e1e4d2f11' User entered 'None (0)'	System	27 Sep 2020 00:34:42
	System	27 Sep 2020 00:34:42

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:19', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ab1b8567-f524-48bd-b708-768e1e4d2f11' User entered 'None (0)'	System	27 Sep 2020 00:34:42
	System	27 Sep 2020 00:34:42

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ab1b8567-f524-48bd-b708-768e1e4d2f11' User entered 'None (0)'	System	27 Sep 2020 00:34:42
	System	27 Sep 2020 00:34:42

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:26', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ab1b8567-f524-48bd-b708-768e1e4d2f11' User entered 'None (0)'	System	27 Sep 2020 00:34:42
	System	27 Sep 2020 00:34:42

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:28', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ab1b8567-f524-48bd-b708-768e1e4d2f11' User entered 'None (0)'	System	27 Sep 2020 00:34:42
	System	27 Sep 2020 00:34:42

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:33', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ab1b8567-f524-48bd-b708-768e1e4d2f11' User entered 'No (N)'	System	27 Sep 2020 00:34:42
	System	27 Sep 2020 00:34:42

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-26T20:34:39', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ab1b8567-f524-48bd-b708-768e1e4d2f11' User entered '26 Sep 2020 20:34'	System	27 Sep 2020 00:34:42
	System	27 Sep 2020 00:34:42

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Sep 2020 14:50:49
User entered 'Day 7'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:19', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3a8c95d2-8d80-47a3-9f58-0de218b5bffd' User entered 'None (0)'	System	27 Sep 2020 16:21:51
	System	27 Sep 2020 16:21:51

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:21', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3a8c95d2-8d80-47a3-9f58-0de218b5bffd' User entered 'None (0)'	System	27 Sep 2020 16:21:51
	System	27 Sep 2020 16:21:51

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:25', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3a8c95d2-8d80-47a3-9f58-0de218b5bffd' User entered 'None (0)'	System	27 Sep 2020 16:21:51
	System	27 Sep 2020 16:21:51

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:30', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3a8c95d2-8d80-47a3-9f58-0de218b5bffd' User entered 'None (0)'	System	27 Sep 2020 16:21:51
	System	27 Sep 2020 16:21:51

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:33', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3a8c95d2-8d80-47a3-9f58-0de218b5bffd' User entered 'None (0)'	System	27 Sep 2020 16:21:51
	System	27 Sep 2020 16:21:51

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:35', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3a8c95d2-8d80-47a3-9f58-0de218b5bffd' User entered 'None (0)'	System	27 Sep 2020 16:21:51
	System	27 Sep 2020 16:21:51

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:40', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3a8c95d2-8d80-47a3-9f58-0de218b5bffd' User entered 'No (N)'	System	27 Sep 2020 16:21:51
	System	27 Sep 2020 16:21:51

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-09-27T12:21:46', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '3a8c95d2-8d80-47a3-9f58-0de218b5bffd' User entered '27 Sep 2020 12:21'	System	27 Sep 2020 16:21:51
	System	27 Sep 2020 16:21:51

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:50:49

US3082081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:50:49

US3082081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	28 Sep 2020 13:03:47

US3082081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '28 Sep 2020'	Erin Harrelson (b) (4)	28 Sep 2020 13:03:47

US3082081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	28 Sep 2020 13:03:47

US3082081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Erin Harrelson (b) (4)	28 Sep 2020 13:03:47

US3082081

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	28 Sep 2020 13:04:23

US3082081

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	28 Sep 2020 13:04:23

US3082081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Angie Northcott (b) (4)	05 Oct 2020 17:00:09

US3082081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '5 Oct 2020'	(b) (4) Angie Northcott (b) (4)	05 Oct 2020 17:00:09

US3082081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Angie Northcott (b) (4)	05 Oct 2020 17:00:09

US3082081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	(b) (4) Angie Northcott (b) (4)	05 Oct 2020 17:00:09

US3082081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) Angie Northcott (b) (4)	05 Oct 2020 17:00:13

US3082081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	05 Oct 2020 17:00:13

US3082081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	12 Oct 2020 13:37:34

US3082081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '12 Oct 2020'	Erin Harrelson (b) (4)	12 Oct 2020 13:37:34

US3082081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	12 Oct 2020 13:37:34

US3082081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Erin Harrelson (b) (4)	12 Oct 2020 13:37:34

US3082081

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	12 Oct 2020 13:37:38

US3082081

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	12 Oct 2020 13:37:38

US3082081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:25:26

US3082081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:25:26

US3082081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:25:26

US3082081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'VISIT3'	System	19 Oct 2020 14:25:26

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '09:43'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '19 Oct 2020 09:43'	System	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'forehead'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '89'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'bpm'	System	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '17'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'breaths/min'	System	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '126'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '79'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'mmHg'	System	19 Oct 2020 14:27:40

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28

US3082081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28

US3082081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:54

US3082081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:54

US3082081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:28:22

US3082081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:28:22

US3082081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '10:17'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:28:22

US3082081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered '19 Oct 2020 10:17'	System	19 Oct 2020 14:28:22

US3082081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:28:31

US3082081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	19 Oct 2020 14:28:31

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 64'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-10-22T13:59:51', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '37501a9a-1fa7-481a-9106-90fbdbdee0e3'	System	22 Oct 2020 18:00:08
User entered 'No (N)'	System	22 Oct 2020 18:00:08

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-10-22T13:59:55', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '37501a9a-1fa7-481a-9106-90fbdbdee0e3'	System	22 Oct 2020 18:00:08
User entered 'No (N)'	System	22 Oct 2020 18:00:08

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-10-22T14:00:05', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '37501a9a-1fa7-481a-9106-90fbdbdee0e3' User entered '22 Oct 2020 14:00:05'	System	22 Oct 2020 18:00:08
	System	22 Oct 2020 18:00:08

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 71'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-10-28T22:15:50', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0eefc68f-cdb4-48e4-95be-dc43eef19981' User entered 'No (N)'	System	29 Oct 2020 02:16:05
	System	29 Oct 2020 02:16:05

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-10-28T22:15:54', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0eefc68f-cdb4-48e4-95be-dc43eef19981'	System	29 Oct 2020 02:16:05
User entered 'No (N)'	System	29 Oct 2020 02:16:05

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-10-28T22:16:03', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '0eefc68f-cdb4-48e4-95be-dc43eef19981' User entered '28 Oct 2020 22:16:03'	System	29 Oct 2020 02:16:05
	System	29 Oct 2020 02:16:05

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 78'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-04T15:01:41', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'a11881d2-be9c-49ca-ad59-ad8f042404df' User entered 'No (N)'	System	04 Nov 2020 20:01:58
	System	04 Nov 2020 20:01:58

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-04T15:01:46', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'a11881d2-be9c-49ca-ad59-ad8f042404df' User entered 'No (N)'	System	04 Nov 2020 20:01:58
	System	04 Nov 2020 20:01:58

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-04T15:01:53', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'a11881d2-be9c-49ca-ad59-ad8f042404df' User entered '04 Nov 2020 15:01:53'	System	04 Nov 2020 20:01:58
	System	04 Nov 2020 20:01:58

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered 'Day 92'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-19T15:54:28', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '41fd3265-a1e5-401d-abc6-d094b4577709' User entered 'No (N)'	System	19 Nov 2020 20:54:56
	System	19 Nov 2020 20:54:56

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-19T15:54:36', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '41fd3265-a1e5-401d-abc6-d094b4577709'	System	19 Nov 2020 20:54:56
User entered 'No (N)'	System	19 Nov 2020 20:54:56

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-19T15:54:53', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '41fd3265-a1e5-401d-abc6-d094b4577709' User entered '19 Nov 2020 15:54:53'	System	19 Nov 2020 20:54:56
	System	19 Nov 2020 20:54:56

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 14:10:25

US3082081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:37:14
Data entry locked.	System	21 Aug 2020 14:10:25
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 14:10:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-24T14:32:53', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'a1478b70-cb2a-4de0-b984-c6dd57b2cd88'	System	24 Nov 2020 19:33:16
User entered 'No (N)'	System	24 Nov 2020 19:33:16

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-24T14:32:59', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'a1478b70-cb2a-4de0-b984-c6dd57b2cd88'	System	24 Nov 2020 19:33:16
User entered 'No (N)'	System	24 Nov 2020 19:33:16

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-24T14:33:07', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'a1478b70-cb2a-4de0-b984-c6dd57b2cd88' User entered '24 Nov 2020 14:33:07'	System	24 Nov 2020 19:33:16
	System	24 Nov 2020 19:33:16

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-30T23:26:22', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '368cdbcd-174f-4136-b96a-0370c91fd881'	System	01 Dec 2020 04:26:42
User entered 'No (N)'	System	01 Dec 2020 04:26:42

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-30T23:26:31', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '368cdbcd-174f-4136-b96a-0370c91fd881'	System	01 Dec 2020 04:26:42
User entered 'No (N)'	System	01 Dec 2020 04:26:42

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-11-30T23:26:40', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '368cdbcd-174f-4136-b96a-0370c91fd881' User entered '30 Nov 2020 23:26:40'	System	01 Dec 2020 04:26:42
	System	01 Dec 2020 04:26:42

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-06T17:39:44', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '389f1371-aa68-48ad-8231-bc6604ea6780' User entered 'No (N)'	System	06 Dec 2020 22:40:03
	System	06 Dec 2020 22:40:03

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-06T17:39:53', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '389f1371-aa68-48ad-8231-bc6604ea6780' User entered 'No (N)'	System	06 Dec 2020 22:40:03
	System	06 Dec 2020 22:40:03

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-06T17:40:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '389f1371-aa68-48ad-8231-bc6604ea6780' User entered '06 Dec 2020 17:40:00'	System	06 Dec 2020 22:40:03
	System	06 Dec 2020 22:40:03

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-14T22:33:16', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '09e98ee0-2f8e-4bae-b043-e79753d8b43a' User entered 'No (N)'	System	15 Dec 2020 03:33:34
	System	15 Dec 2020 03:33:34

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-14T22:33:23', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '09e98ee0-2f8e-4bae-b043-e79753d8b43a'	System	15 Dec 2020 03:33:34
User entered 'No (N)'	System	15 Dec 2020 03:33:34

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-14T22:33:30', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '09e98ee0-2f8e-4bae-b043-e79753d8b43a' User entered '14 Dec 2020 22:33:30'	System	15 Dec 2020 03:33:34
	System	15 Dec 2020 03:33:34

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-21T21:00:14', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd7e09804-5ae6-4fc5-a79e-1affe8e9cc0d' User entered 'No (N)'	System	22 Dec 2020 02:00:28
	System	22 Dec 2020 02:00:28

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-21T21:00:19', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd7e09804-5ae6-4fc5-a79e-1affe8e9cc0d' User entered 'No (N)'	System	22 Dec 2020 02:00:28

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-21T21:00:26', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd7e09804-5ae6-4fc5-a79e-1affe8e9cc0d' User entered '21 Dec 2020 21:00:26'	System	22 Dec 2020 02:00:28

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-27T08:49:52', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c52ff6f3-7dc7-4eaa-92ad-168d2a27ee30'	System	27 Dec 2020 13:50:08
User entered 'No (N)'	System	27 Dec 2020 13:50:08

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-27T08:49:58', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c52ff6f3-7dc7-4eaa-92ad-168d2a27ee30'	System	27 Dec 2020 13:50:08
User entered 'No (N)'	System	27 Dec 2020 13:50:08

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2020-12-27T08:50:05', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c52ff6f3-7dc7-4eaa-92ad-168d2a27ee30' User entered '27 Dec 2020 08:50:05'	System	27 Dec 2020 13:50:08
	System	27 Dec 2020 13:50:08

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-04T10:32:33', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f955f6da-2bf3-4800-af67-8ac1f20e8e8f' User entered 'No (N)'	System	04 Jan 2021 15:32:49
	System	04 Jan 2021 15:32:49

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-04T10:32:39', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f955f6da-2bf3-4800-af67-8ac1f20e8e8f'	System	04 Jan 2021 15:32:49
User entered 'No (N)'	System	04 Jan 2021 15:32:49

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-04T10:32:44', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'f955f6da-2bf3-4800-af67-8ac1f20e8e8f' User entered '04 Jan 2021 10:32:44'	System	04 Jan 2021 15:32:49

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-10T19:34:16', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c5f79c07-18f0-44fb-afbf-1c5256782b71' User entered 'No (N)'	System	11 Jan 2021 00:34:37

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-10T19:34:22', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c5f79c07-18f0-44fb-afbf-1c5256782b71'	System	11 Jan 2021 00:34:37
User entered 'No (N)'	System	11 Jan 2021 00:34:37

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-10T19:34:34', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'c5f79c07-18f0-44fb-afbf-1c5256782b71' User entered '10 Jan 2021 19:34:34'	System	11 Jan 2021 00:34:37

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-17T10:40:14', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'fb8cee5e-cf4b-4bff-b698-df0ac36b764c' User entered 'No (N)'	System	17 Jan 2021 15:40:28

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-17T10:40:20', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'fb8cee5e-cf4b-4bff-b698-df0ac36b764c' User entered 'No (N)'	System	17 Jan 2021 15:40:28

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-17T10:40:25', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'fb8cee5e-cf4b-4bff-b698-df0ac36b764c' User entered '17 Jan 2021 10:40:25'	System	17 Jan 2021 15:40:28

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-24T08:49:12', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'b03c9186-492a-4188-baf1-707d9683d277'	System	24 Jan 2021 13:49:31
User entered 'No (N)'	System	24 Jan 2021 13:49:31

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-24T08:49:20', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'b03c9186-492a-4188-baf1-707d9683d277'	System	24 Jan 2021 13:49:31
User entered 'No (N)'	System	24 Jan 2021 13:49:31

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-24T08:49:28', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'b03c9186-492a-4188-baf1-707d9683d277'	System	24 Jan 2021 13:49:31
User entered '24 Jan 2021 08:49:28'	System	24 Jan 2021 13:49:31

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-31T16:49:51', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ae969144-04fb-414a-ac76-fcf6e0d382a6' User entered 'No (N)'	System	31 Jan 2021 21:50:10

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-31T16:49:56', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ae969144-04fb-414a-ac76-fcf6e0d382a6' User entered 'No (N)'	System	31 Jan 2021 21:50:10

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-01-31T16:50:06', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ae969144-04fb-414a-ac76-fcf6e0d382a6'	System	31 Jan 2021 21:50:10
User entered '31 Jan 2021 16:50:06'	System	31 Jan 2021 21:50:10

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-07T15:05:18', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7f7efe1a-f85f-48da-8496-0de6063536f4' User entered 'No (N)'	System	07 Feb 2021 20:05:40
	System	07 Feb 2021 20:05:40

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-07T15:05:25', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7f7efe1a-f85f-48da-8496-0de6063536f4'	System	07 Feb 2021 20:05:40
User entered 'No (N)'	System	07 Feb 2021 20:05:40

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-07T15:05:32', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7f7efe1a-f85f-48da-8496-0de6063536f4'	System	07 Feb 2021 20:05:40
User entered '07 Feb 2021 15:05:32'	System	07 Feb 2021 20:05:40

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-14T15:50:02', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7c15fff9-ecf4-4354-ab71-0754cdc9895d' User entered 'No (N)'	System	14 Feb 2021 20:50:17
	System	14 Feb 2021 20:50:17

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-14T15:50:06', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7c15fff9-ecf4-4354-ab71-0754cdc9895d' User entered 'No (N)'	System	14 Feb 2021 20:50:17

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-14T15:50:12', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '7c15fff9-ecf4-4354-ab71-0754cdc9895d' User entered '14 Feb 2021 15:50:12'	System	14 Feb 2021 20:50:17
	System	14 Feb 2021 20:50:17

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-21T10:41:50', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5eca08ff-bcf7-4a47-9894-b2521de936cc'	System	21 Feb 2021 15:42:04
User entered 'No (N)'	System	21 Feb 2021 15:42:04

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-21T10:41:55', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5eca08ff-bcf7-4a47-9894-b2521de936cc'	System	21 Feb 2021 15:42:04
User entered 'No (N)'	System	21 Feb 2021 15:42:04

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-21T10:42:01', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '5eca08ff-bcf7-4a47-9894-b2521de936cc' User entered '21 Feb 2021 10:42:01'	System	21 Feb 2021 15:42:04
	System	21 Feb 2021 15:42:04

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-28T18:02:31-05:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'e2b38d9e-9603-4b13-b7f5-4f53e2342f3d' User entered 'No (N)'	System	28 Feb 2021 23:08:07
	System	28 Feb 2021 23:08:07

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-28T18:02:36-05:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'e2b38d9e-9603-4b13-b7f5-4f53e2342f3d' User entered 'No (N)'	System	28 Feb 2021 23:08:07
	System	28 Feb 2021 23:08:07

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-28T18:02:42-05:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'e2b38d9e-9603-4b13-b7f5-4f53e2342f3d' User entered '28 Feb 2021 23:02:42'	System	28 Feb 2021 23:08:07
	System	28 Feb 2021 23:08:07

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-07T09:33:11-05:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '566f4f4d-ec28-48f1-a2f1-a44b82600b96'	System	07 Mar 2021 14:33:32
User entered 'No (N)'	System	07 Mar 2021 14:33:32

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-07T09:33:19-05:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '566f4f4d-ec28-48f1-a2f1-a44b82600b96'	System	07 Mar 2021 14:33:32
User entered 'No (N)'	System	07 Mar 2021 14:33:32

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-07T09:33:27-05:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '566f4f4d-ec28-48f1-a2f1-a44b82600b96' User entered '07 Mar 2021 09:33:27'	System	07 Mar 2021 14:33:32
	System	07 Mar 2021 14:33:32

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-14T14:46:24-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '17f4acb9-5a2b-484a-890a-5f15f77b2dd4'	System	14 Mar 2021 18:46:41
User entered 'No (N)'	System	14 Mar 2021 18:46:41

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-14T14:46:32-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '17f4acb9-5a2b-484a-890a-5f15f77b2dd4'	System	14 Mar 2021 18:46:41
User entered 'No (N)'	System	14 Mar 2021 18:46:41

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-14T14:46:39-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '17f4acb9-5a2b-484a-890a-5f15f77b2dd4' User entered '14 Mar 2021 14:46:39'	System	14 Mar 2021 18:46:41
	System	14 Mar 2021 18:46:41

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-21T13:43:37-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'da09d1b2-10db-434b-8b6d-5943cbd29bd9'	System	21 Mar 2021 17:43:49
User entered 'No (N)'	System	21 Mar 2021 17:43:49

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-21T13:43:41-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'da09d1b2-10db-434b-8b6d-5943cbd29bd9'	System	21 Mar 2021 17:43:49
User entered 'No (N)'	System	21 Mar 2021 17:43:49

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-21T13:43:46-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'da09d1b2-10db-434b-8b6d-5943cbd29bd9'	System	21 Mar 2021 17:43:49
User entered '21 Mar 2021 13:43:46'	System	21 Mar 2021 17:43:49

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-28T14:38:22-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4711ea71-d3fd-40bf-a5dc-599237468ee1' User entered 'No (N)'	System	28 Mar 2021 18:38:38
	System	28 Mar 2021 18:38:38

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-28T14:38:27-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4711ea71-d3fd-40bf-a5dc-599237468ee1' User entered 'No (N)'	System	28 Mar 2021 18:38:38
	System	28 Mar 2021 18:38:38

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-03-28T14:38:33-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '4711ea71-d3fd-40bf-a5dc-599237468ee1' User entered '28 Mar 2021 14:38:33'	System	28 Mar 2021 18:38:38
	System	28 Mar 2021 18:38:38

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-04T15:59:49-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2059a2ce-e048-4043-afad-b07c70ae0214'	System	04 Apr 2021 20:00:10
User entered 'No (N)'	System	04 Apr 2021 20:00:10

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-04T16:00:02-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2059a2ce-e048-4043-afad-b07c70ae0214'	System	04 Apr 2021 20:00:10
User entered 'No (N)'	System	04 Apr 2021 20:00:10

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-04T16:00:08-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '2059a2ce-e048-4043-afad-b07c70ae0214'	System	04 Apr 2021 20:00:10
User entered '04 Apr 2021 16:00:08'	System	04 Apr 2021 20:00:10

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-11T00:16:12-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '6fbc5050-df77-41e7-bc94-f9f06f548b58'	System	11 Apr 2021 04:16:27
User entered 'No (N)'	System	11 Apr 2021 04:16:27

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-11T00:16:16-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '6fbc5050-df77-41e7-bc94-f9f06f548b58'	System	11 Apr 2021 04:16:27
User entered 'No (N)'	System	11 Apr 2021 04:16:27

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-11T00:16:23-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: '6fbc5050-df77-41e7-bc94-f9f06f548b58'	System	11 Apr 2021 04:16:27
User entered '11 Apr 2021 00:16:23'	System	11 Apr 2021 04:16:27

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-18T15:25:41-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'b4a4f31b-d390-4d3b-9e1a-1a0f7ef50195'	System	18 Apr 2021 19:25:55
User entered 'No (N)'	System	18 Apr 2021 19:25:55

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-18T15:25:47-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'b4a4f31b-d390-4d3b-9e1a-1a0f7ef50195'	System	18 Apr 2021 19:25:55
User entered 'No (N)'	System	18 Apr 2021 19:25:55

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-18T15:25:52-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'b4a4f31b-d390-4d3b-9e1a-1a0f7ef50195'	System	18 Apr 2021 19:25:55
User entered '18 Apr 2021 15:25:52'	System	18 Apr 2021 19:25:55

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-25T20:04:03-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ff316670-c153-4868-9759-3bc07ac602a6'	System	26 Apr 2021 00:04:19
User entered 'No (N)'	System	26 Apr 2021 00:04:19

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-25T20:04:08-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ff316670-c153-4868-9759-3bc07ac602a6'	System	26 Apr 2021 00:04:19
User entered 'No (N)'	System	26 Apr 2021 00:04:19

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-04-25T20:04:14-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'ff316670-c153-4868-9759-3bc07ac602a6'	System	26 Apr 2021 00:04:19
User entered '25 Apr 2021 20:04:14'	System	26 Apr 2021 00:04:19

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-05-03T14:21:26-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd745b63b-ffcf-4211-92bc-0671ede15fb0'	System	03 May 2021 18:21:38
User entered 'No (N)'	System	03 May 2021 18:21:38

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

Have you been exposed to someone with 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 (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-05-03T14:21:30-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd745b63b-ffcf-4211-92bc-0671ede15fb0'	System	03 May 2021 18:21:38
User entered 'No (N)'	System	03 May 2021 18:21:38

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-05-03T14:21:35-04:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'd745b63b-ffcf-4211-92bc-0671ede15fb0'	System	03 May 2021 18:21:38
User entered '03 May 2021 14:21:35'	System	03 May 2021 18:21:38

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:25:25

US3082081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:25:25
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:25:25

US3082081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:03:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-27T17:28:49-05:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'dbdca326-97d1-4d54-b886-ce75b77644d0'		27 Feb 2021 22:29:04
User entered 'No (N)'	System	27 Feb 2021 22:29:04

US3082081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:03:57

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:49:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC8224D7-005D-489E-A1B5-CE0191978EBB)', Time: '2021-02-27T17:29:01-05:00', User OID: 'PatientReportedOutcome (US3082081)', ODM File OID: 'dbdca326-97d1-4d54-b886-ce75b77644d0'	System	27 Feb 2021 22:29:04
User entered '27 Feb 2021 22:29:01'	System	27 Feb 2021 22:29:04

US3082081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	16 Nov 2020 15:44:16

US3082081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '16 Nov 2020'	Erin Harrelson (b) (4)	16 Nov 2020 15:44:16

US3082081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	16 Nov 2020 15:44:16

US3082081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Erin Harrelson (b) (4)	16 Nov 2020 15:44:16

US3082081

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	16 Nov 2020 15:44:19

US3082081

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 21:16:28
User entered 'I'	System	16 Nov 2020 15:44:19

US3082081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	21 Dec 2020 17:45:13

US3082081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '21 Dec 2020'	Erin Harrelson (b) (4)	21 Dec 2020 17:45:13

US3082081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	21 Dec 2020 17:45:13

US3082081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	Erin Harrelson (b) (4)	21 Dec 2020 17:45:13

US3082081

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	21 Dec 2020 17:45:20

US3082081

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User entered 'I'	System	21 Dec 2020 17:45:20

US3082081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	21 Jan 2021 17:02:48

US3082081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)-	19 Feb 2021 17:48:21
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 25JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:27:35
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 25JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'updated' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	04 Feb 2021 13:32:46
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 25JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:07:50
User entered '21 Jan 2021'	Erin Harrelson (b) (4) (b) (4)	21 Jan 2021 17:02:48

US3082081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	21 Jan 2021 17:02:48

US3082081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Erin Harrelson (b) (4)	21 Jan 2021 17:02:48

US3082081

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	21 Jan 2021 17:03:21

US3082081

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User entered 'I'	System	21 Jan 2021 17:03:21

US3082081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	18 Feb 2021 19:14:04

US3082081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered '18 Feb 2021'	Erin Harrelson (b) (4)	18 Feb 2021 19:14:04

US3082081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4)	18 Feb 2021 19:14:04

US3082081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered empty.	Erin Harrelson (b) (4)	18 Feb 2021 19:14:04

US3082081

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	18 Feb 2021 19:14:19

US3082081

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:33:46
User entered 'I'	System	18 Feb 2021 19:14:19

US3082081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	19 Mar 2021 17:47:25

US3082081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered '19 Mar 2021'	Erin Harrelson (b) (4)	19 Mar 2021 17:47:25

US3082081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'Clinic (Clinic)'	Erin Harrelson (b) (4)	19 Mar 2021 17:47:25

US3082081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User entered 'VISIT4'	System	19 Mar 2021 17:47:25

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'No (N)'	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User entered empty.	System	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User entered empty.	System	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User entered empty.	System	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User entered empty.	System	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User entered empty.	System	30 Mar 2021 18:50:28

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03

US3082081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03

US3082081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Angie Northcott (b) (4)	30 Mar 2021 18:50:20
User entered 'Yes (Y)'	(b) (4)	
	Erin Harrelson (b) (4)	19 Mar 2021 17:47:57
	(b) (4)	

US3082081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty; reason for change Data Entry Error	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:50:20
User entered '19 Mar 2021'	(b) (4) Erin Harrelson (b) (4)	19 Mar 2021 17:47:57
	(b) (4)	

US3082081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	19 Mar 2021 17:48:48

US3082081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered '19 Mar 2021'	Erin Harrelson (b) (4)	19 Mar 2021 17:48:48

US3082081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered '11:13'	Erin Harrelson (b) (4)	19 Mar 2021 17:48:48

US3082081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User entered '19 Mar 2021 11:13'	System	19 Mar 2021 17:48:48

US3082081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	19 Mar 2021 18:55:32

US3082081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:54:03
User entered 'I'	System	19 Mar 2021 18:55:32

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	04 Feb 2021 13:33:16

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '25 Jan 2021'	Ayssa Valente (b) (4)	04 Feb 2021 13:33:16

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[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 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Clinic (Clinic)'	Ayssa Valente (b) (4)	04 Feb 2021 13:33:16

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 13:33:16

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '25 Jan 2021'	Ayssa Valente (b) (4)	04 Feb 2021 13:33:45

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

[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 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:14:04

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	04 Feb 2021 13:33:45

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:14:04

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '25 Jan 2021'	Ayssa Valente (b) (4)	04 Feb 2021 13:33:45

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'mRNA-1273 (mRNA-1273)'	Ayssa Valente (b) (4)	04 Feb 2021 13:33:45

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
Signature has been broken.	Angie Northcott (b) (4)	30 Mar 2021 18:58:00
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Angie Northcott (b) (4)	30 Mar 2021 18:58:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Placebo (Placebo)'	Ayssa Valente (b) (4)	04 Feb 2021 13:33:45

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
Signature has been broken.	Angie Northcott (b) (4)	30 Mar 2021 18:58:00
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Angie Northcott (b) (4)	30 Mar 2021 18:58:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Placebo (Placebo)'	Ayssa Valente (b) (4)	04 Feb 2021 13:33:45

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User closed query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	(b) (4)	
Query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' answered by data change (Site from System).	System	30 Mar 2021 18:58:07
Signature has been broken.	System	30 Mar 2021 18:58:07
User entered 'No (N)' reason for change: Data Entry Error	Angie Northcott (b) (4)	30 Mar 2021 18:58:07
User opened query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	Angie Northcott (b) (4)	30 Mar 2021 18:58:07
User signature succeeded.	System	30 Mar 2021 18:58:00
User entered 'Yes (Y)'	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
	Ayssa Valente (b) (4)	04 Feb 2021 13:33:45
	(b) (4)	

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	30 Mar 2021 18:58:00
User entered 'I'	System	04 Feb 2021 13:33:45

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:03:57

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	30 Mar 2021 18:58:00
User entered 'I'	System	04 Feb 2021 13:33:45

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '74.0' in	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '221.0' lb	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '74.0' in	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '221.0' lb	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User accepted default value 'Pre-Dose (PREDOSE)'	Ayssa Valente (b) (4) (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '25 Jan 2021'	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '10:19'	(b) (4) Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered '25 Jan 2021 10:19'	System	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '98.7' F	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Oral (Oral)'	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	(b) (4) Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '80'	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered 'bpm'	System	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '17'	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered 'breaths/min'	System	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '131'	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered 'mmHg'	System	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '75'	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered 'mmHg'	System	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '74.0' in	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '221.0' lb	Ayssa Valente (b) (4)	04 Feb 2021 13:34:47

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User accepted default value 'Post-Dose (POSTDOSE)'	Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'No (N)'	Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	(b) (4) Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered empty.	Ayssa Valente (b) (4)	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	04 Feb 2021 13:36:15

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	04 Feb 2021 13:36:25

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '25 Jan 2021'	Ayssa Valente (b) (4)	04 Feb 2021 13:36:25

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Mar 2021 18:59:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 18:59:35
User entered 'No (N)' reason for change: Data Entry Error	Angie Northcott (b) (4)	30 Mar 2021 18:59:35
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 18:59:25
User entered empty; reason for change Data Entry Error	Angie Northcott (b) (4)	30 Mar 2021 18:59:25
User entered 'No (N)'	Angie Northcott (b) (4)	30 Mar 2021 18:54:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'Other (OTHER)' reason for change: Data Entry Error	Angie Northcott (b) (4)	30 Mar 2021 18:59:35
User entered empty; reason for change Data Entry Error	Angie Northcott (b) (4)	30 Mar 2021 18:59:25
User entered 'Other (OTHER)'	Angie Northcott (b) (4)	30 Mar 2021 18:54:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

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 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'PARTICIPANT RECEIVED 2 DOSES OF MRNA' reason for change: Data Entry Error	Angie Northcott (b) (4)	30 Mar 2021 18:59:35
User entered empty; reason for change Data Entry Error	Angie Northcott (b) (4)	30 Mar 2021 18:59:25
User entered 'Participant received 2 doses of mRNA'	Angie Northcott (b) (4)	30 Mar 2021 18:54:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
DataPoint set to visible.	System	30 Mar 2021 18:58:00
User entered empty.	System	30 Mar 2021 18:54:02
DataPoint set to invisible.	System	04 Feb 2021 13:33:45

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	Angie Northcott (b) (4)	30 Mar 2021 18:54:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:54:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	30 Mar 2021 18:54:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered empty.	Angie Northcott (b) (4)	30 Mar 2021 18:54:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	30 Mar 2021 18:54:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:57

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered empty.	System	30 Mar 2021 18:54:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	04 Feb 2021 13:36:44

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '25 Jan 2021'	Ayssa Valente (b) (4)	04 Feb 2021 13:36:44

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '10:50' reason for change: Data Entry Error	Ayssa Valente (b) (4)	04 Feb 2021 13:37:20
User entered '10:53'	Ayssa Valente (b) (4)	04 Feb 2021 13:36:44

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered '25 Jan 2021 10:50'	System	04 Feb 2021 13:37:20
User entered '25 Jan 2021 10:53'	System	04 Feb 2021 13:36:44

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'Yes (Y)'	Ayssa Valente (b) (4)	04 Feb 2021 13:37:07

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '25 Jan 2021'	Ayssa Valente (b) (4)	04 Feb 2021 13:37:07

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '10:53'	Ayssa Valente (b) (4)	04 Feb 2021 13:37:07

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:57

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered '25 Jan 2021 10:53'	System	04 Feb 2021 13:37:07

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:22:12
User entered 'Yes (Y)'	(b) (4) Angie Northcott (b) (4)	30 Mar 2021 18:55:02

US3082081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:29
User entered 'I'	System	30 Mar 2021 18:55:02

US3082081

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:03:57

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:22:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 13:05:09
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:04:37

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User closed query 'Please update AEs to include Hives (01Oct20).' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 13:29:54
Query 'Please update AEs to include Hives (01Oct20).' answered with 'AE log updated' (Site from CRA).	Flo Abbott (b) (4)	30 Oct 2020 17:26:49
User opened query 'Please update AEs to include Hives (01Oct20).' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 13:52:35

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:25:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:25:49
Data point term sent to Coder	System	17 Nov 2020 18:10:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
Data point term sent to Coder	System	05 Nov 2020 17:23:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 22:49:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 22:49:46
Data point term sent to Coder	System	21 Sep 2020 18:06:38
User entered 'bursitis [right arm/shoulder]'	Ayssa Valente (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '10 Sep 2020'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered empty.	System	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:59:13
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated to add end date' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	12 Jan 2021 15:57:57
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	12 Jan 2021 15:57:02
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	12 Jan 2021 15:57:02
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 06:13:48
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	12 Jan 2021 15:57:20
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	12 Jan 2021 15:57:20
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Jan 2021 15:57:02
DataPoint Un-verified.	Ayssa Valente (b) (4)	12 Jan 2021 15:57:02
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4)	12 Jan 2021 15:57:02
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	12 Jan 2021 15:57:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
	Ayssa Valente (b) (4)	21 Sep 2020 18:06:31
	(b) (4)	

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered empty.	System	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Not Related (NOT RELATED)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Not Related (NOT RELATED)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'None (NONE)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'I'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Un-verified.	(b) (4) Ayssa Valente (b) (4)	12 Jan 2021 15:57:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	12 Jan 2021 15:57:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

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 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered '0'	System	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered '1'	System	21 Sep 2020 18:06:31

US3082081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:55:18
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:35:47
User entered	System	06 Oct 2020 14:35:40
'USA-US114-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	06 Oct 2020 14:35:40

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:40:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:40:51
	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 18:10:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
Data point term sent to Coder	System	05 Nov 2020 17:23:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 12:35:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 12:35:20
	(b) (4)	
Data point term sent to Coder	System	12 Oct 2020 12:34:45
Data point term sent to Coder	System	12 Oct 2020 12:34:45
User closed query 'For coding purposes, please split CHOLECYSTITIS/CHOLECYSTECTOMY into separate entries' (Site from System).	System	12 Oct 2020 12:34:44
Query 'For coding purposes, please split CHOLECYSTITIS/CHOLECYSTECTOMY into separate entries' answered with 'cholecystectomy is a concomitant procedure, the AE is cholecystitis, new entry does not need to be made.' (Site from System).	Brandy Lowman (b) (4)	12 Oct 2020 12:34:44
User entered 'CHOLECYSTITIS' reason for change: Data Entry Error	Brandy Lowman (b) (4)	12 Oct 2020 12:34:30
User opened query 'For coding purposes, please split CHOLECYSTITIS/CHOLECYSTECTOMY into separate entries' (Site from System).	Coder Import (b) (4)	07 Oct 2020 13:43:24
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 20:02:46
User entered 'Cholecystitis/Cholecystectomy'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Yes (Y)'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'No (N)'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'No (N)'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '02 Oct 2020'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered empty.	System	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Please verify if this AE is still ongoing as it was noted that a Laparoscopic Cholecystectomy was performed as treatment for this AE. Please review and update as appropriate. Otherwise, clarify.' (Site from DM). DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 06:41:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
Query 'Per DM CLR: Please verify if this AE is still ongoing as it was noted that a Laparoscopic Cholecystectomy was performed as treatment for this AE. Please review and update as appropriate. Otherwise, clarify.' answered with 'Endate updated' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:00:34
DataPoint Un-verified.	Flo Abbott (b) (4)	30 Oct 2020 16:45:58
User entered 'No (N)' reason for change: Data Entry Error	Flo Abbott (b) (4)	30 Oct 2020 16:45:35
User opened query 'Per DM CLR: Please verify if this AE is still ongoing as it was noted that a Laparoscopic Cholecystectomy was performed as treatment for this AE. Please review and update as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 16:45:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Oct 2020 06:14:07
	(b) (4), (b) (6)	22 Oct 2020 13:51:00
	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
	(b) (4), (b) (6)	03 Nov 2020 14:00:37
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:53:20
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Oct 2020 16:46:39
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	30 Oct 2020 16:46:39
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Endate updated' (Site from Safety).	Flo Abbott (b) (4)	30 Oct 2020 16:46:12
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Oct 2020 16:45:35
User entered '19 Oct 2020' reason for change: Data Entry Error	Flo Abbott (b) (4)	30 Oct 2020 16:45:35
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 13:53:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:34:17
User entered empty.	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered empty.	System	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Grade 3/Severe (Grade 3/Severe)'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Yes (Y)'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

Death

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		07 Oct 2020 11:11:18
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		07 Oct 2020 11:11:18
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Oct 2020 20:02:06
User entered 'I'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '02 Oct 2020'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '05 Oct 2020' reason for change: Data Entry Error	Flo Abbott (b) (4)	07 Oct 2020 11:11:18
User entered empty.	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
	(b) (4), (b) (6)	22 Oct 2020 13:51:00
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	07 Oct 2020 11:11:18
Query 'Admitted to ICU? is Unknown. However, this System 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).		07 Oct 2020 11:11:18
User entered 'No (N)' reason for change: Data Entry Error	Flo Abbott (b) (4)	07 Oct 2020 11:11:18
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	05 Oct 2020 20:02:06
User entered 'Unknown (UNK)'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'I'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 13:51:00
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:42:01
User closed query 'Data is required. Please complete.' (Site from System).	Flo Abbott (b) (4)	07 Oct 2020 11:11:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 11:08:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	07 Oct 2020 11:08:27
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	Flo Abbott (b) (4)	07 Oct 2020 11:08:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 17:47:15
User entered empty.	System	05 Oct 2020 20:02:06
	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6))	22 Oct 2020 13:51:00
User entered 'Not Related (NOT RELATED)'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User closed query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 13:51:00
Query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED. ' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:18:44
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	14 Oct 2020 14:20:32
User opened query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4)	
User entered 'None (NONE)'	(b) (4)	
	Morgan Mathis (b) (4)	13 Oct 2020 17:46:36
	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 15:35:24
	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

None

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered '0'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'I'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'I'	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:00:55
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'outcome updated' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:53:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Flo Abbott (b) (4)	30 Oct 2020 16:46:54
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 16:46:39
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 14:22:12
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	13 Oct 2020 15:35:14
	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User entered empty.	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
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) (4), (b) (6)	30 Nov 2020 15:02:13
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:02:11
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:02:07
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 'Updated. Per medical records a covid test was not performed. ' (Site from Safety).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 15:19:44
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'Updated. The subject does not have any risk factors associated. ' (Site from Safety).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 15:19:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Relevant lab tests have been added. ' (Site from Safety).	Megan Marles (b) (4) (b) (4)	27 Nov 2020 15:19:19
DataPoint Un-verified.	Megan Marles (b) (4) (b) (4)	27 Nov 2020 15:19:09

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD ACUTE ONSET OF EPIGASTRIC ABDOMINAL PAIN, NAUSEA AND VOMITING ON 02OCT2020. Abdomen CT with IV contrast showed the gallbladder mildly distended with slight infiltration of surrounding fat, which suggested cholecystitis. Labs collected on 02Oct2020 showed elevated Alkaline Phosphatase (result: 123, reference range 46-116 U/L) and Elevated Bilirubin, Direct (result: 0.6, reference range <=0.3 mg/dL) and Elevated Bilirubin, Total (result: 1.6, reference range 0.3-1.2 mg/dL) which can be indicative of gallbladder disease. IT WAS DETERMINED LAPAROSCOPIC CHOLESYSTECTOMY SHOULD BE DONE. PATIENT TOLERATED IT WELL AND PAIN WAS CONTROLLED. SUBJECT WAS DISCHARGED ON 05OCT2020 AT 1800. The patient is a male, non-obese patient, with no history of diabetes or other risk factors present for cholecystitis. A covid test was not performed during hospitalization.' reason for change: Data Entry Error	Megan Marles (b) (4)	27 Nov 2020 15:19:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:32:51
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:32:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:32:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:44

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Narrative](#)

Audit	User	Time (GMT)
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)	30 Oct 2020 19:53:39
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:53:31
User closed query 'PV Query: Please provide results of radiological studies, surgical report for cholecystectomy, and any pathology results.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:53:04
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Final Pathologic Diagnosis: Gangrenous cholecystitis' (Site from Safety).	Flo Abbott (b) (4)	30 Oct 2020 17:21:26
Query 'PV Query: Please provide results of radiological studies, surgical report for cholecystectomy, and any pathology results.' answered with 'CT: abd/plevis: Gallbladder mildly distended with slight infiltration of surrounding fat may suggest cholecystitis in the appropriate clinical setting. Colon is decompressed with appearance of apparent wall thickening in the transverse, descending and sigmoid' (Site from Safety).	Flo Abbott (b) (4)	30 Oct 2020 17:17:26
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 'No record of any covid 19 testing found' (Site from Safety).	Flo Abbott (b) (4)	30 Oct 2020 17:12:53
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.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 14:58:08

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 13:53:33
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 13:51:00
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:35:33
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)	13 Oct 2020 15:35:03
User opened query 'PV Query: Please provide results of radiological studies, surgical report for cholecystectomy, and any pathology results.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:34:38
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)	13 Oct 2020 15:34:03
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Oct 2020 11:09:27
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	07 Oct 2020 11:09:27
User entered 'Subject had acute onset of epigastric abdominal pain, nausea and vomiting on 02Oct2020. After radiological studies it was determined laparoscopic cholecystectomy should be done. Patient tolerated it well and pain was controlled. Subject was discharged on 05Oct2020 at 1800' reason for change: Data Entry Error	Flo Abbott (b) (4)	07 Oct 2020 11:09:27
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Flo Abbott (b) (4)	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered 'I'	System	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered 'I'	System	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered '0'	System	05 Oct 2020 20:02:06

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:10:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:10:49
Data point term sent to Coder	System	17 Nov 2020 18:10:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
Data point term sent to Coder	System	05 Nov 2020 17:23:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 17:26:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 17:26:55
Data point term sent to Coder	System	30 Oct 2020 17:26:27
User entered 'Hives'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'No (N)'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'No (N)'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'No (N)'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '01 Oct 2020'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered empty.	System	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'No (N)'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
DataPoint Un-verified.	Morgan Mathis (b) (4)	20 Nov 2020 15:43:05
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 15:43:05
DataPoint activated with code reason code Data required.	(b) (4)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '01 Oct 2020'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered empty.	System	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
DataPoint Un-verified.	Morgan Mathis (b) (4)	20 Nov 2020 15:43:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	20 Nov 2020 15:43:05
reason for change: Data Entry Error	Morgan Mathis (b) (4)	20 Nov 2020 15:43:05
DataPoint activated with code reason code Data	(b) (4)	17 Nov 2020 18:09:53
required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not	(b) (4), (b) (6)	05 Nov 2020 17:22:43
required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'No (N)'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'Related (RELATED)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	20 Nov 2020 15:43:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Nov 2020 05:11:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:01:05
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
Query 'Data is required. Please complete.' answered with 'awaiting PI assessment' (Site from System).	Flo Abbott (b) (4)	30 Oct 2020 17:26:12
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 17:25:44
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'Not Related (NOT RELATED)'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:53
User closed query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Kindly review and update this field as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 21:03:48
Query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Kindly review and update this field as appropriate.' answered with 'ACTION WAS CORRECTED' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 15:58:10
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:58:02
User entered 'Not Applicable (NOT APPLICABLE) reason for change: Data Entry Error	(b) (6)	04 Nov 2020 15:58:02
User opened query 'Per CDM: Per page 38 of CCGs V2.0, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Kindly review and update this field as appropriate.' (Site from DM).	(b) (6)	04 Nov 2020 15:40:54
DataPoint Verified.	(b) (6)	03 Nov 2020 14:00:55
User entered 'None (NONE)'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'I'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered '0'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered empty.	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:55
User entered 'Subject had hives and he took benadryl and they resolved'	Flo Abbott (b) (4)	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered '0'	System	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43
User entered '0'	System	30 Oct 2020 17:25:44

US3082081

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User coded data point as SOC: Gastrointestinal disorders, HLG: 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)	17 Nov 2020 18:24:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:24:48
Data point term sent to Coder	System	17 Nov 2020 18:23:42
User entered 'Constipation'	Morgan Mathis (b) (4) (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	20 Nov 2020 15:45:25
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'No (N)'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'No (N)'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '5 Oct 2020'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered empty.	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User entered empty.	System	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'No (N)'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '4 Nov 2020'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered empty.	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User entered empty.	System	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'No (N)'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '0'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '0'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '0'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered empty.	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered empty.	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered empty.	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered empty.	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '0'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '0'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '0'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'Not Related (NOT RELATED)'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'Not Related (NOT RELATED)'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'Not Applicable (NOT APPLICABLE)'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '0'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'l'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered '0'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered empty.	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:57:13
User entered empty.	Morgan Mathis (b) (4)	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User entered '0'	System	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
User entered '1'	System	20 Nov 2020 15:45:25
User entered '0'	System	17 Nov 2020 18:23:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 22:33:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 18:09:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 17:22:43

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:03:57

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:22:55
User signature succeeded.	Barton Williams (b) (4)-	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:39:57
User closed query 'Per ETRTR: Please add medication dosed for SAE "Cholecystitis", thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 13:39:53
Query 'Per ETRTR: Please add medication dosed for SAE "Cholecystitis", thanks.' answered with 'Medication has been added.' (Site from CRA).	Alice Cipollini (b) (4) (b) (4)	14 Oct 2020 19:43:41
User opened query 'Per ETRTR: Please add medication dosed for SAE "Cholecystitis", thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 18:26:56
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 13:59:40

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
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: DEXLANSOPRAZOLE, PRODUCTSYNONYM: DEXILANT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:22:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:22:20
Data point term sent to Coder	System	21 Aug 2020 14:20:58
User entered 'Dexilant'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Esophsgitis'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '60'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'every other day (QOD)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '01 Jan 2017'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Alice Cipollini (b) (4) (b) (4)	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:20:47

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:08:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:08:41
Data point term sent to Coder	System	24 Aug 2020 16:07:55
User entered 'advil'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User closed query 'Per CDM, per DM CLR re-query: Response is noted. However, per section 8.3.4 of the protocol, solicited adverse reactions reported in the e-diary need to be recorded on the AE eCRF IF they meet the AE reporting criteria as specified by the DM CLR query. Please review and confirm in a query response that the solicited adverse reaction of INJECTION SITE PAIN does not meet the AE reporting criteria, else add an entry to the AE page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:46:37
Query 'Per CDM, per DM CLR re-query: Response is noted. However, per section 8.3.4 of the protocol, solicited adverse reactions reported in the e-diary need to be recorded on the AE eCRF IF they meet the AE reporting criteria as specified by the DM CLR query. Please review and confirm in a query response that the solicited adverse reaction of INJECTION SITE PAIN does not meet the AE reporting criteria, else add an entry to the AE page as appropriate. ' answered with 'Confirm, does not meet AE reporting criteria' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	21 Oct 2020 12:53:00
User opened query 'Per CDM, per DM CLR re-query: Response is noted. However, per section 8.3.4 of the protocol, solicited adverse reactions reported in the e-diary need to be recorded on the AE eCRF IF they meet the AE reporting criteria as specified by the DM CLR query. Please review and confirm in a query response that the solicited adverse reaction of INJECTION SITE PAIN does not meet the AE reporting criteria, else add an entry to the AE page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:14:57

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:14:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.	Erin Harrelson (b) (4)	08 Oct 2020 15:59:43
' answered with 'injection site pain was not reported as AE because this was noted in e-diary.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:30:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

1847 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User entered 'injection site pain'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '200'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'twice daily (BID)'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '22 Aug 2020'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '22 Aug 2020'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User closed query 'Per DM CLR: Per DM CLR: Was this medication taken for solicited event?=NO; however, there is a record of this event in the diary. Review if this is correct and be ticked as Yes. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 04:44:18
Query 'Per DM CLR: Per DM CLR: Was this medication taken for solicited event?=NO; however, there is a record of this event in the diary. Review if this is correct and be ticked as Yes. Else, provide clarification.' answered with 'Corrected to 'yes" (Site from DM).	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:04:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:04:42
User opened query 'Per DM CLR: Per DM CLR: Was this medication taken for solicited event?=NO; however, there is a record of this event in the diary. Review if this is correct and be ticked as Yes. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:47:17
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User entered '2'	System	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User entered '1'	System	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:46
User entered '804 (804)'	System	24 Aug 2020 16:07:02

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:23:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:23:55
Data point term sent to Coder	System	21 Sep 2020 14:10:22
Coding entries removed.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:09:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 17:37:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 17:37:48
Data point term sent to Coder	System	25 Aug 2020 16:47:32
User entered 'Advil'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of Pain if known.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:58:34
Query 'Per DM CLR: Please update the indication to reflect the location and type of Pain if known.' answered with 'indication has been updated' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:09:57
User entered 'general PAIN PREVENTATIVE' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:09:48
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of Pain if known.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:47:38
User entered 'Pain Preventative'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '200'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'as needed (PRN)'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '23 Aug 2020' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	09 Sep 2020 13:13:06
User entered '24 Aug 2020'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 16:47:11

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:10:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:10:05
Data point term sent to Coder	System	21 Sep 2020 14:47:50
Coding entries removed.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:46:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:36:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:36:41
Data point term sent to Coder	System	21 Sep 2020 14:34:19
User entered 'aleve'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)-	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'R ARM/shoulder BURSITIS' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:46:53
User entered 'r arm bursitis'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '500'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'twice daily (BID)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '11 Sep 2020'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '14 Sep 2020'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User entered '2'	System	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User entered '1'	System	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:15:50
User entered '804 (804)'	System	21 Sep 2020 14:33:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:20:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:20:47
Data point term sent to Coder	System	21 Sep 2020 14:46:49
Data point term sent to Coder	System	21 Sep 2020 14:35:23
User entered 'prednisone'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'R ARM/shoulder BURSITIS' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:46:43
User entered 'r arm bursitis'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '10'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'other (OTHER)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'titrated 6 days - 6 : 5 : 4 : 3 : 2 : 1'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '12 Sep 2020'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '17 Sep 2020'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User entered empty.	System	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User entered empty.	System	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:00
User entered empty.	System	21 Sep 2020 14:34:42

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:32:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:32:48
Data point term sent to Coder	System	21 Sep 2020 14:46:45
Data point term sent to Coder	System	21 Sep 2020 14:36:24
User entered 'steroid shot'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'R ARM/shoulder BURSITIS' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:46:25
User entered 'r arm bursitis'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'I'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Other (OTHER)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'injection'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intramuscular (INTRAMUSCULAR)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '11 Sep 2020'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '11 Sep 2020'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User entered empty.	System	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User entered empty.	System	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:04
User entered empty.	System	21 Sep 2020 14:35:25

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:53:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:53:34
Data point term sent to Coder	System	09 Oct 2020 15:08:09
User entered 'BENADRYL'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'HIVES (ARMS & LEGS)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '50'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'as needed (PRN)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '1 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:12:22
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'UPDATED' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	03 Nov 2020 15:23:50
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	03 Nov 2020 15:23:42
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:03:22
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:11:15
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User entered empty.	System	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User entered empty.	System	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:06
User entered empty.	System	09 Oct 2020 15:07:23

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 18:38:21
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 Oct 2020 18:38:21
Data point term sent to Coder	System	12 Oct 2020 18:37:32
Coding entries removed.	Morgan Mathis (b) (4) (b) (4)	12 Oct 2020 18:37:11
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)	09 Oct 2020 15:13:25
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 Oct 2020 15:13:25
Data point term sent to Coder	System	09 Oct 2020 15:12:14
User entered 'ACETAMINOPHEN'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#2) that match.es this medication. If yes, please update 'Prophylaxis' as appropriate.	(b) (4), (b) (6)	09 Nov 2020 12:12:31
' (Site from DM).		
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#2) that match.es this medication. If yes, please update 'Prophylaxis' as appropriate.	Morgan Mathis (b) (4)	03 Nov 2020 17:10:09
' answered with 'UPDATED.' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	03 Nov 2020 17:10:02
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:03:31
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded (AE#2) that match.es this medication. If yes, please update 'Prophylaxis' as appropriate.	(b) (4), (b) (6)	03 Nov 2020 11:11:35
' (Site from DM).		
User entered 'Yes (Y)'	Morgan Mathis (b) (4)	09 Oct 2020 15:11:33
	(b) (4)	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'PAIN RELIEVER FOR CHOLECYSTITIS' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	12 Oct 2020 18:37:11
User entered 'PAIN RELIEVER'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '650'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'other (OTHER)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'EVERY 6 HOURS AS NEEDED'	Morgan Mathis (b) (4)	09 Oct 2020 15:11:33
	(b) (4)	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '5 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Morgan Mathis (b) (4)	09 Oct 2020 15:11:33
	(b) (4)	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:11:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 00:01:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 00:01:31
Data point term sent to Coder	System	12 Oct 2020 18:37:30
Coding entries removed.	Morgan Mathis (b) (4) (b) (4)	12 Oct 2020 18:37:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:30:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:30:28
Data point term sent to Coder	System	09 Oct 2020 15:13:18
User entered 'OXYCODONE'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'PAIN RELIEVER FOR CHOLECYSTITIS' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	12 Oct 2020 18:37:27
User entered 'PAIN RELIEVER'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '5'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'other (OTHER)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'EVERY 6 HOURS AS NEEDED'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '5 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 09:31:47
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Updated' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 17:38:20
DataPoint Un-verified.	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 17:38:14
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	07 Dec 2020 17:38:14
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 11:34:18
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Un-verified.	Alice Cipollini (b) (4)	07 Dec 2020 17:38:14
User entered '19 Oct 2020' reason for change: New Information	Alice Cipollini (b) (4)	07 Dec 2020 17:38:14
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User entered empty.	System	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User entered empty.	System	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:15
User entered empty.	System	09 Oct 2020 15:13:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
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: SENNOSIDES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:16:35
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 Oct 2020 15:16:35
Data point term sent to Coder	System	09 Oct 2020 15:15:21
User entered 'SENNOSIDES'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR(re-query): AE form is unlocked, please review and update AE form as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 10:37:58
Query 'Per DM CLR(re-query): AE form is unlocked, please review and update AE form as appropriate. Thank you.' answered with 'ae updated' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	19 Nov 2020 14:07:48
User opened query 'Per DM CLR(re-query): AE form is unlocked, please review and update AE form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:21:10
User closed query 'Per DM CLR re-query: Per response however there is no change reflecting in AE form, kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:21:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
Query 'Per DM CLR re-query: Per response however there is no change reflecting in AE form, kindly review and update as appropriate.' answered with 'The AEs for this patient have been locked and we cannot update the form on our end. We are in the process of trying to have it unlocked.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 13:54:50
User opened query 'Per DM CLR re-query: Per response however there is no change reflecting in AE form, kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:15:57
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that match.es this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:15:57

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that match.es this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'AE has been recorded. Waiting for PI to sign off on it. ' (Site from DM).	Morgan Mathis (b) (4)	03 Nov 2020 19:57:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:03:41
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that match.es this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:12:04
User entered 'CONSTIPATION'	Morgan Mathis (b) (4)	09 Oct 2020 15:14:21
	(b) (4)	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '8.6'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'as needed (PRN)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '5 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:58:18
DataPoint Un-verified.	Morgan Mathis (b) (4)	20 Nov 2020 16:40:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Morgan Mathis (b) (4)	20 Nov 2020 16:40:30
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:58:18
DataPoint Un-verified.	Morgan Mathis (b) (4)	20 Nov 2020 16:40:30
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 16:40:30
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Morgan Mathis (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User entered empty.	System	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User entered empty.	System	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:17
User entered empty.	System	09 Oct 2020 15:14:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:23:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:23:18
Data point term sent to Coder	System	14 Oct 2020 18:40:50
User entered 'IOPAMIDOL'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is a contrast agent. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:16:07
Query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is a contrast agent. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly. ' answered with 'data is updated' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:19:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:19:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:03:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is a contrast agent. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:12:17
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'CONTRAST AGENT'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '100'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mL (mL)'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User entered empty.	System	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User entered empty.	System	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:20
User entered empty.	System	14 Oct 2020 18:40:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, TERTIARY AMINES, PRODUCT: HYOSCYAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 11:32:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 11:32:41
Data point term sent to Coder	System	26 Feb 2021 12:59:28
Coding entries removed.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 12:58:35
User signature succeeded.	(b) (4), (b) (6)	19 Feb 2021 17:48:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, TERTIARY AMINES, PRODUCT: HYOSCYAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:56:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:56:55
Data point term sent to Coder	System	14 Dec 2020 13:18:40
Coding entries removed.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:17:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, TERTIARY AMINES, PRODUCT: HYOSCYAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:40:39

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Morgan Mathis (b) (4) (b) (4) (b) (4), (b) (6)	10 Nov 2020 21:40:39 03 Nov 2020 20:01:02 03 Nov 2020 20:00:28 03 Nov 2020 14:02:37
DataPoint Verified.		
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, TERTIARY AMINES, PRODUCT: HYOSCYAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 21:16:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'HYOSCYAMINE'	Coder Import (b) (4) (b) (4) System Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 21:16:17 14 Oct 2020 18:42:56 14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Also, indication states Abdominal spasms from SAE. Cholecystitis is recorded in AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:01:36
Query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Also, indication states Abdominal spasms from SAE. Cholecystitis is recorded in AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'updated to NO' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:34:02
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:33:55
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:33:55
User opened query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Also, indication states Abdominal spasms from SAE. Cholecystitis is recorded in AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:11:30
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:50:12

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:41:07
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Yes (Y)'	Erin Harrelson (b) (4)	14 Oct 2020 18:42:20
	(b) (4)	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:09:37
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:59:06
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Indication updated for clarity' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 12:58:46
Signature has been broken.	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 12:58:35
User entered 'CHOLECYSTITIS' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	26 Feb 2021 12:58:35
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 08:18:53
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antispasmodic) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Spasms etc.). Ensure that the indication is reconciled with AE eCRF. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 19:11:29

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antispasmodic) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Spasms etc.). Ensure that the indication is reconciled with AE eCRF. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4)	14 Dec 2020 13:17:54
DataPoint Un-verified.	(b) (4)	
User entered 'Abdominal Spasms (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4)	14 Dec 2020 13:17:46
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antispasmodic) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Spasms etc.). Ensure that the indication is reconciled with AE eCRF. Update as appropriate.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Dec 2020 16:43:58
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:08:56
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate.' answered with 'goes with SAE.' (Site from DM).	Morgan Mathis (b) (4)	09 Nov 2020 12:20:25
User entered 'ANTI-SPASMODIC (from SAE)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 20:00:35
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 20:00:28
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:04:05
	(b) (4), (b) (6)	03 Nov 2020 14:02:37

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:12:29
User entered 'ANTI-SPASMODIC'	Erin Harrelson (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '250'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'ug (ug)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User entered empty.	System	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User entered empty.	System	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:32
User entered empty.	System	14 Oct 2020 18:42:20

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFOTETAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 15:57:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 15:57:19
Data point term sent to Coder	System	28 Jan 2021 13:45:53
Coding entries removed.	Ayssa Valente (b) (4)	28 Jan 2021 13:45:31
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFOTETAN DISODIUM, PRODUCTSYNONYM: CEFOTETAN [CEFOTETAN DISODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:54:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:54:32
Data point term sent to Coder	System	14 Oct 2020 18:42:56
User entered 'CEFOTETAN'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:21:08
Query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly. ' answered with 'updated. ' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	03 Nov 2020 20:00:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	03 Nov 2020 20:00:48
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:04:15
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:12:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Indication = Prophylaxis (Infection Preventative). Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe (AE#2 Cholecystitis). If yes, please update indication and prophylaxis field as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:03:17
Query 'Per DM CLR: Indication = Prophylaxis (Infection Preventative). Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe (AE#2 Cholecystitis). If yes, please update indication and prophylaxis field as appropriate. ' answered with 'Updated indication' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:46:03
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:45:31
User entered 'AE #2 (CHOLECYSTITIS)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:45:31
User opened query 'Per DM CLR: Indication = Prophylaxis (Infection Preventative). Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe (AE#2 Cholecystitis). If yes, please update indication and prophylaxis field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:09:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'INFECTION PREVENTATIVE'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'g (g)'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:56
User entered 'twice daily (BID)' reason for change: Data Entry Error	Brandy Lowman (b) (4)	17 Nov 2020 14:18:16
DataPoint Un-verified.	Brandy Lowman (b) (4)	17 Nov 2020 14:18:10
User entered 'once daily (QD)' reason for change: Data Entry Error	Brandy Lowman (b) (4)	17 Nov 2020 14:18:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per CDM: "Twice daily" is one of the option present in the drop down list in Frequency. Kindly choose that and remove the data from here else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 05:12:13
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
Query 'Per CDM: "Twice daily" is one of the option present in the drop down list in Frequency. Kindly choose that and remove the data from here else clarify.' answered with 'Freq updated to drop down twice daily appropriately.' (Site from DM).	Brandy Lowman (b) (4)	17 Nov 2020 14:18:31
DataPoint Un-verified.	Brandy Lowman (b) (4)	17 Nov 2020 14:18:10
User entered empty; reason for change Data Entry Error	Brandy Lowman (b) (4)	17 Nov 2020 14:18:10
User opened query 'Per CDM: "Twice daily" is one of the option present in the drop down list in Frequency. Kindly choose that and remove the data from here else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:51:12
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'TWICE'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Un-verified.	(b) (4) Ayssa Valente (b) (4)	28 Jan 2021 13:45:36
User entered '3 Oct 2020' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	28 Jan 2021 13:45:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:58:18
DataPoint Un-verified.	Morgan Mathis (b) (4)	20 Nov 2020 16:41:51
User entered '3 Oct 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 16:41:51
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User entered '2'	System	17 Nov 2020 14:18:16
User entered '1'	System	17 Nov 2020 14:18:10
User entered empty.	System	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User entered '1'	System	17 Nov 2020 14:18:10
User entered empty.	System	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:36
User entered '804 (804)'	System	17 Nov 2020 14:18:10
User entered empty.	System	14 Oct 2020 18:42:30

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE HYDROCHLORIDE, PRODUCTSYNONYM: LIDOCAINE VISCOUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:17:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:17:22
Data point term sent to Coder	System	14 Oct 2020 18:45:00
User entered 'LIDOCAINE VISCOUS'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:21:33
Query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly. ' answered with 'No. It was used to treat pain. ' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	03 Nov 2020 20:25:35
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:04:27
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:12:52
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'LOCAL ANESTHETIC'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '10'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mL (mL)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User entered empty.	System	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User entered empty.	System	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:40
User entered empty.	System	14 Oct 2020 18:44:33

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:47:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:47:43
Data point term sent to Coder	System	14 Dec 2020 13:42:43
Coding entries removed.	Erin Harrelson (b) (4)	14 Dec 2020 13:42:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:01:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:01:19
Data point term sent to Coder	System	03 Nov 2020 20:02:04
Coding entries removed.	Morgan Mathis (b) (4)	03 Nov 2020 20:01:52
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 05:31:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

2085 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 05:31:27
Data point term sent to Coder	(b) (4)	
User entered 'ENOXAPARIN LOVENOX' reason for change: Data Entry Error	System	14 Oct 2020 18:46:07
Data point term sent to Coder	(b) (4), (b) (6)	14 Oct 2020 18:46:06
User entered 'ENOXAPARIN'		
	System	14 Oct 2020 18:43:57
	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Un-verified.	(b) (4)	
	Erin Harrelson (b) (4)	14 Dec 2020 13:43:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	14 Dec 2020 13:43:23
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. To prevent complications of cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:12:03
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. To prevent complications of cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:43:19
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:42:08
User entered 'Thrombosis prophylaxis (FROM SAE) reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:42:08
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. To prevent complications of cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:15:56
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Pulmonary embolism etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:15:49

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Pulmonary embolism etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:55:10
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antispasmodic) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Pulmonary embolism etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:54:48
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antispasmodic) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Pulmonary embolism etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:53:41
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:21:46
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate.' answered with 'from SAE' (Site from DM).	Morgan Mathis (b) (4)	03 Nov 2020 20:02:02
User entered 'ANITCOAGULANT (from SAE)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	03 Nov 2020 20:01:52

PRODUCTION RELEASE (v12.003
EAB) (1725)

2089 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:04:42
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:13:07
User entered 'ANITCOAGULANT'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '40'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User entered empty.	System	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User entered empty.	System	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:44
User entered empty.	System	14 Oct 2020 18:43:52

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
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)	17 Dec 2020 21:40:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 21:40:01
Data point term sent to Coder	System	14 Dec 2020 13:54:45
Coding entries removed.	Erin Harrelson (b) (4)	14 Dec 2020 13:54:31
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)	04 Nov 2020 20:32:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:32:28
Data point term sent to Coder	System	03 Nov 2020 20:03:05
Coding entries removed.	Morgan Mathis (b) (4)	03 Nov 2020 20:02:21
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
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)	15 Oct 2020 05:39:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 05:39:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

2106 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	14 Oct 2020 18:46:05
User entered 'HYDROMORPHONE DILAUDID'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:12:18
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:54:50
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:54:31
User entered 'Abdominal pain from cholecystitis (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:54:31
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:15:21
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:15:06

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:56:35
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.	(b) (4), (b) (6)	09 Nov 2020 12:21:53
' (Site from DM).		
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.	Morgan Mathis (b) (4)	03 Nov 2020 20:02:29
' answered with 'was from SAE' (Site from DM).	(b) (4)	
User entered 'PAIN MANAGEMENT (from SAE)'	Morgan Mathis (b) (4)	03 Nov 2020 20:02:21
reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:04:51
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.	(b) (4), (b) (6)	03 Nov 2020 11:13:17
' (Site from DM).		
User entered 'PAIN MANAGEMENT'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '.5'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'SEVEN TIMES'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '5 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User entered empty.	System	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User entered empty.	System	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:57
User entered empty.	System	14 Oct 2020 18:45:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 19:15:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 19:15:57
Data point term sent to Coder	System	14 Dec 2020 13:55:46
Coding entries removed.	Erin Harrelson (b) (4)	14 Dec 2020 13:55:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 08:08:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 08:08:52
Data point term sent to Coder	System	03 Nov 2020 20:03:05
Coding entries removed.	Morgan Mathis (b) (4)	03 Nov 2020 20:02:42
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 04:47:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 04:47:26

PRODUCTION RELEASE (v12.003
EAB) (1725)

2126 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	14 Oct 2020 18:47:10
User entered 'PROMETHAZINE'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Un-verified.	(b) (4)	
	Erin Harrelson (b) (4)	14 Dec 2020 13:55:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	14 Dec 2020 13:55:18
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anti nausea) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. To prevent Nausea from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:12:28
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anti nausea) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. To prevent Nausea from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:55:24
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:55:18
User entered 'Nausea prophylaxis (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:55:18
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anti nausea) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. To prevent Nausea from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:14:16
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anti nausea) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Nausea etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:14:01

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anti nausea) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Nausea etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Dec 2020 16:57:35
	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that match.es this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:21:59
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that match.es this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' ' answered with 'was from SAE' (Site from DM).	Morgan Mathis (b) (4)	03 Nov 2020 20:02:49
User entered 'ANIT-NAUSEA (from SAE)' reason for change: Data Entry Error DataPoint Un-verified.	Morgan Mathis (b) (4)	03 Nov 2020 20:02:42
	(b) (4), (b) (6)	03 Nov 2020 14:04:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that match.es this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:13:27
User entered 'ANIT-NAUSEA'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '6.25'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (does not correspond with the dosage used). Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:18:48
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (does not correspond with the dosage used). Please update route as appropriate. ' answered with 'this patient was hospitalized and given this through an IV' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:33:37
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (does not correspond with the dosage used). Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:13:48
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User entered empty.	System	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User entered empty.	System	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:01
User entered empty.	System	14 Oct 2020 18:47:09

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH ANTIFLATULENTS, PRODUCT: ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE, PRODUCTSYNONYM: MAALOX PLUS EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Jan 2021 15:24:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 15:24:19
Data point term sent to Coder	System	28 Jan 2021 13:46:54
Coding entries removed.	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:46:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH ANTIFLATULENTS, PRODUCT: ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE, PRODUCTSYNONYM: MAALOX [ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:48:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:48:06
Data point term sent to Coder	System	14 Dec 2020 13:56:46
Coding entries removed.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:55:57

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH ANTIFLATULENTS, PRODUCT: ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE, PRODUCTSYNONYM: MAALOX [ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:13:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:13:37
Data point term sent to Coder	System	03 Nov 2020 20:03:05
Coding entries removed.	Morgan Mathis (b) (4) (b) (4)	03 Nov 2020 20:03:02
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH ANTIFLATULENTS, PRODUCT: ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE, PRODUCTSYNONYM: MAALOX [ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 20:58:04
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 Oct 2020 20:58:04
Data point term sent to Coder	System	14 Oct 2020 18:49:16
User entered 'Aluminum/magnesium/simethicone (maalox)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:09:37
User closed query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis field be updated to No. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 13:44:55
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis field be updated to No. Otherwise, provide clarification.' answered with 'Prophylaxis answer updated to No' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	24 Feb 2021 12:53:06
Signature has been broken.	Ayssa Valente (b) (4) (b) (4)	24 Feb 2021 12:52:54
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	24 Feb 2021 12:52:54
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis field be updated to No. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 08:05:49
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 17:48:18
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:55:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:55:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication and prophylaxis field as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:17:30
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication and prophylaxis field as appropriate. ' answered with 'updated to AE' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:46:54
User entered 'AE #2 [CHOLECYSTITIS]' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:46:47
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication and prophylaxis field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:10:47
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Cholecystitis prophylaxis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 19:12:37

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Cholecystitis prophylaxis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM). DataPoint Un-verified.	Erin Harrelson (b) (4)	14 Dec 2020 13:56:25
	(b) (4)	
User entered 'Cholecystitis prophylaxis (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4)	14 Dec 2020 13:55:57
	(b) (4)	
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Cholecystitis prophylaxis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:12:41
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Gastritis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:12:33
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Gastritis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:58:45
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:22:06
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' answered with 'was from SAE' (Site from DM).	Morgan Mathis (b) (4)	03 Nov 2020 20:03:16
User entered 'ANTIACID/ANTIGAS (From SAE)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 20:03:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:05:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:13:40
User entered 'antacid/antigas'	Erin Harrelson (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '200/200/20'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User entered empty.	System	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User entered empty.	System	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:04
User entered empty.	System	14 Oct 2020 18:49:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
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)	17 Dec 2020 19:02:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:02:46
Data point term sent to Coder	System	14 Dec 2020 13:21:41
Coding entries removed.	Erin Harrelson (b) (4)	14 Dec 2020 13:20:42
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)	04 Nov 2020 14:02:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 14:02:22
Data point term sent to Coder	System	03 Nov 2020 20:04:06
Coding entries removed.	Morgan Mathis (b) (4)	03 Nov 2020 20:03:30
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
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)	15 Oct 2020 05:34:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 05:34:22
Data point term sent to Coder	System	14 Oct 2020 18:49:16
User entered 'FENTANYL'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:12:45
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:20:48
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:20:42
User entered 'Abdominal pain from cholecystitis (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:20:42
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:12:01
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:11:51

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 16:59:22
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.	(b) (4), (b) (6)	09 Nov 2020 12:22:11
' (Site from DM).		
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.	Morgan Mathis (b) (4)	03 Nov 2020 20:03:38
' answered with 'was from SAE' (Site from DM).	(b) (4)	
User entered 'PAIN MANAGEMENT (from SAE)'	Morgan Mathis (b) (4)	03 Nov 2020 20:03:30
reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:05:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.	(b) (4), (b) (6)	03 Nov 2020 11:13:50
' (Site from DM).		
User entered 'PAIN MANAGEMENT'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)-	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '50'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:08:37
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'updated for correctness' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:51:20
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:51:05
User entered 'ug (ug)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:51:05
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:12:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:58:18
DataPoint Un-verified.	Morgan Mathis (b) (4)	20 Nov 2020 16:45:25
User entered 'other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Morgan Mathis (b) (4)	20 Nov 2020 16:45:25
User closed query ' Per CDM: "Twice daily" is one of the option present in the drop down list in Frequency. Kindly choose that and remove the data from here else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 05:12:21
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
Query ' Per CDM: "Twice daily" is one of the option present in the drop down list in Frequency. Kindly choose that and remove the data from here else clarify.' answered with 'Frequency updated appropriately to once daily, med used twice total so once for each of the two days listed.' (Site from DM).	Brandy Lowman (b) (4)	17 Nov 2020 14:16:15
DataPoint Un-verified.	Brandy Lowman (b) (4)	17 Nov 2020 14:16:08
User entered 'once daily (QD)' reason for change:	Brandy Lowman (b) (4)	17 Nov 2020 14:16:08
Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 13:49:48
User opened query ' Per CDM: "Twice daily" is one of the option present in the drop down list in Frequency. Kindly choose that and remove the data from here else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:02:37
DataPoint Verified.	(b) (4), (b) (6)	
User entered 'other (OTHER)'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:58:18
DataPoint Un-verified.	Morgan Mathis (b) (4)	20 Nov 2020 16:45:25
User entered 'TWICE' reason for change: Data Entry Error	(b) (4) Morgan Mathis (b) (4)	20 Nov 2020 16:45:25
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
DataPoint Un-verified.	Brandy Lowman (b) (4)	17 Nov 2020 14:16:08
User entered empty; reason for change Data Entry Error	Brandy Lowman (b) (4)	17 Nov 2020 14:16:08
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'TWICE'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '3 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User entered empty.	System	20 Nov 2020 16:45:25
User entered 'I'	System	17 Nov 2020 14:16:08
User entered empty.	System	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User entered empty.	System	20 Nov 2020 16:45:25
User entered 'I'	System	17 Nov 2020 14:16:08
User entered empty.	System	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:07
User entered empty.	System	20 Nov 2020 16:45:25
User entered '804 (804)'	System	17 Nov 2020 14:16:08
User entered empty.	System	14 Oct 2020 18:49:08

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:47:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:47:43
Data point term sent to Coder	System	14 Dec 2020 13:57:47
Coding entries removed.	Erin Harrelson (b) (4)	14 Dec 2020 13:57:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:01:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:01:20
Data point term sent to Coder	System	03 Nov 2020 20:05:10
Coding entries removed.	Morgan Mathis (b) (4)	03 Nov 2020 20:04:18
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 05:31:27

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'enoxaparin lovenox'	Coder Import (b) (4) (b) (4) System Erin Harrelson (b) (4) (b) (4)	15 Oct 2020 05:31:27 14 Oct 2020 18:51:24 14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Un-verified.	Erin Harrelson (b) (4)	14 Dec 2020 13:57:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4)	14 Dec 2020 13:57:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. To prevent complications of cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:13:03
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. To prevent complications of cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:57:32
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:57:25
User entered 'Thrombosis prophylaxis (FROM SAE) reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 13:57:25
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. To prevent complications of cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:11:30
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Pulmonary embolism etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:11:21

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (anticoagulant) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Pulmonary embolism etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Dec 2020 17:00:16
	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:22:16
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate.' answered with 'was from SAE' (Site from DM).	Morgan Mathis (b) (4)	03 Nov 2020 20:04:54
User entered 'ANTICOAGULANT (from SAE)' reason for change: Data Entry Error DataPoint Un-verified.	Morgan Mathis (b) (4)	03 Nov 2020 20:04:18
	(b) (4), (b) (6)	03 Nov 2020 14:05:16
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:14:00
User entered 'anticoagulant'	Erin Harrelson (b) (4)	14 Oct 2020 18:51:04
	(b) (4)	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '40'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)-	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '04 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '04 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User entered empty.	System	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User entered empty.	System	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:10
User entered empty.	System	14 Oct 2020 18:51:04

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
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)	17 Dec 2020 21:40:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 21:40:01
Data point term sent to Coder	System	14 Dec 2020 14:03:49
Coding entries removed.	Erin Harrelson (b) (4)	14 Dec 2020 14:03:10
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)	04 Nov 2020 20:17:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:17:28
Data point term sent to Coder	System	03 Nov 2020 20:11:24
Coding entries removed.	Morgan Mathis (b) (4)	03 Nov 2020 20:10:55
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
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)	15 Oct 2020 05:39:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 05:39:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

2206 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	14 Oct 2020 18:51:24
User entered 'HYDROMORPHONE DILAUDID'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:13:11
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:03:19
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:03:10
User entered 'Abdominal pain from cholecystitis (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:03:10
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:08:51
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:08:29

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Dec 2020 17:00:44
	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:22:22
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' ' answered with 'from SAE' (Site from DM).	Morgan Mathis (b) (4)	03 Nov 2020 20:11:05
User entered 'PAIN MANAGEMENT (from SAE)' reason for change: Data Entry Error DataPoint Un-verified.	Morgan Mathis (b) (4)	03 Nov 2020 20:10:55
	(b) (4), (b) (6)	03 Nov 2020 14:05:23
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:14:08
User entered 'PAIN MANAGEMENT'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '.25'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Un-verified.	(b) (4)	
	Morgan Mathis (b) (4)	18 Dec 2020 13:48:24
User entered 'four times daily (QID)' reason for change: Data Entry Error	(b) (4)	
	Morgan Mathis (b) (4)	18 Dec 2020 13:48:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'other (OTHER)'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per CDM: Kindly check if this can be selected from one of the option present in frequency and remove it from here else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 09:02:28
Query 'Per CDM: Kindly check if this can be selected from one of the option present in frequency and remove it from here else clarify.' answered with 'updated' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	18 Dec 2020 13:48:30
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	18 Dec 2020 13:48:24
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	18 Dec 2020 13:48:24
User opened query 'Per CDM: Kindly check if this can be selected from one of the option present in frequency and remove it from here else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 09:47:05
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'FOUR TIMES'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '3 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '3 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User entered '4'	System	18 Dec 2020 13:48:24
User entered empty.	System	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User entered '1'	System	18 Dec 2020 13:48:24
User entered empty.	System	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:12
User entered '804 (804)'	System	18 Dec 2020 13:48:24
User entered empty.	System	14 Oct 2020 18:51:05

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
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)	14 Dec 2020 14:05:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 14:05:19
Data point term sent to Coder	System	14 Dec 2020 14:03:51
Coding entries removed.	Erin Harrelson (b) (4)	14 Dec 2020 14:03:41
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)	03 Nov 2020 20:13:26
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 20:13:26
Data point term sent to Coder	System	03 Nov 2020 20:12:27
Coding entries removed.	Morgan Mathis (b) (4)	03 Nov 2020 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
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)	14 Oct 2020 18:54:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:54:30
Data point term sent to Coder	System	14 Oct 2020 18:53:32
User entered 'Acetaminophen'	Erin Harrelson (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:13:22
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:03:49
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:03:41
User entered 'Abdominal pain (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:03:41
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:01:08
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:22:27

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'from SAE' (Site from DM).	Morgan Mathis (b) (4)	03 Nov 2020 20:12:07
User entered 'PAIN MANAGEMENT (from SAE)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 20:11:39
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:05:29
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:14:17
User entered 'pain management'	Erin Harrelson (b) (4)	14 Oct 2020 18:52:45
	(b) (4)	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '650'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'four times daily (QID)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '05 Oct 2020' reason for change: Data Entry Error	Erin Harrelson (b) (4)	14 Oct 2020 18:55:12
User entered '02 Oct 2020'	(b) (4) Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User entered '4'	System	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User entered '1'	System	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:26
User entered '804 (804)'	System	14 Oct 2020 18:52:45

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Nov 2020 14:31:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 14:31:15
Data point term sent to Coder	System	25 Nov 2020 13:25:31
Coding entries removed.	Ayssa Valente (b) (4) (b) (4)	25 Nov 2020 13:24:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:59:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:59:18
Data point term sent to Coder	System	03 Nov 2020 20:17:49
Coding entries removed.	Morgan Mathis (b) (4) (b) (4)	03 Nov 2020 20:17:44
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:33:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:33:22
Data point term sent to Coder	System	14 Oct 2020 18:53:29
User entered 'MIDAZOLAM'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per CDM, CLR re-query: As per the response indication from SAE, however SAE is recorded as Cholecystitis. Please review reconcile and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 05:20:29
Query 'Per CDM, CLR re-query: As per the response indication from SAE, however SAE is recorded as Cholecystitis. Please review reconcile and update accordingly. Otherwise clarify. Thank you.' answered with 'Cholecystectomy procedure is correct indication. Updated' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	25 Nov 2020 13:24:40
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	25 Nov 2020 13:24:36
User entered 'ANESTHESIA (FROM Cholecystectomy)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	25 Nov 2020 13:24:36
User opened query 'Per CDM, CLR re-query: As per the response indication from SAE, however SAE is recorded as Cholecystitis. Please review reconcile and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:35:54
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that match.es this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:33:50
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that match.es this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'from SAE' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	03 Nov 2020 20:17:50
User entered 'ANESTHESIA (From SAE)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	03 Nov 2020 20:17:44

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:05:37
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:14:32
User entered 'ANESTHESIA'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '2'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '3 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '3 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User entered empty.	System	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User entered empty.	System	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:30
User entered empty.	System	14 Oct 2020 18:52:41

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Dec 2020 10:11:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 10:11:37
Data point term sent to Coder	System	14 Dec 2020 14:04:51
Coding entries removed.	Erin Harrelson (b) (4)	14 Dec 2020 14:04:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 11:52:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:52:35
Data point term sent to Coder	System	03 Nov 2020 20:22:55
Coding entries removed.	Morgan Mathis (b) (4)	03 Nov 2020 20:22:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:39:17
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 Oct 2020 22:39:17
Data point term sent to Coder	System	14 Oct 2020 18:53:33
User entered 'Oxycodone'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:14:12
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:04:23
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:04:17
User entered 'Abdominal pain from cholecystitis (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:04:17
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain from cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:07:29
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:07:22

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (pain management) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Abdominal Pain etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:02:23
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.	(b) (4), (b) (6)	09 Nov 2020 12:22:37
' (Site from DM).		
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.	Morgan Mathis (b) (4)	03 Nov 2020 20:23:00
' answered with 'was from SAE' (Site from DM).	(b) (4)	
User entered 'PAIN MANAGEMENT (from SAE)'	Morgan Mathis (b) (4)	03 Nov 2020 20:22:49
reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:05:43
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.	(b) (4), (b) (6)	03 Nov 2020 11:14:43
' (Site from DM).		
User entered 'Pain management'	Erin Harrelson (b) (4)	14 Oct 2020 18:53:28
	(b) (4)	

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '5'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'twice daily (BID)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '05 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User entered '2'	System	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User entered '1'	System	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:33
User entered '804 (804)'	System	14 Oct 2020 18:53:28

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE;LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:17:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:17:22
Data point term sent to Coder	System	14 Oct 2020 18:57:47
User entered 'LIDOCANE 1%, BUPRIVICANE .25%'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'LOCAL (ABDOMIN) ANESTHESIA'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '40'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mL (mL)'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '3 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '3 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User entered empty.	System	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User entered empty.	System	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:36
User entered empty.	System	14 Oct 2020 18:56:54

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
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.	(b) (4) Coder Import (b) (4)	29 Jan 2021 10:09:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 10:09:16
Data point term sent to Coder	System	28 Jan 2021 13:52:57
Coding entries removed.	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:52:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 10:12:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 10:12:46
Data point term sent to Coder	System	14 Dec 2020 14:05:52
Coding entries removed.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:04:55
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)	06 Nov 2020 11:52:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Morgan Mathis (b) (4) (b) (4) (b) (4), (b) (6)	06 Nov 2020 11:52:34 03 Nov 2020 20:23:59 03 Nov 2020 20:23:25 03 Nov 2020 14:02:37
DataPoint Verified.		
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)	14 Oct 2020 22:39:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Pantoprazole'	Coder Import (b) (4) (b) (4) System Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 22:39:17 14 Oct 2020 18:54:37 14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:09:37
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis field be updated to No. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 13:45:07
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis field be updated to No. Otherwise, provide clarification. ' answered with 'Prophylaxis answer updated to No' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	24 Feb 2021 12:53:35
Signature has been broken.	Ayssa Valente (b) (4) (b) (4)	24 Feb 2021 12:53:21
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	24 Feb 2021 12:53:21
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis field be updated to No. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 08:06:42
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 17:48:18
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:04:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	14 Dec 2020 14:04:55
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication and prophylaxis field as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:17:57
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication and prophylaxis field as appropriate. ' answered with 'updated indication' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:53:13
User entered 'AE #2 [CHOLECYSTITIS]' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:52:05
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication and prophylaxis field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:13:05
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Cholecystitis prophylaxis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 19:14:32

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Cholecystitis prophylaxis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM). DataPoint Un-verified.	Erin Harrelson (b) (4)	14 Dec 2020 14:05:06
	(b) (4)	
User entered 'Cholecystitis prophylaxis (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4)	14 Dec 2020 14:04:55
	(b) (4)	
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Cholecystitis prophylaxis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:06:19
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Cholecystectomy prophylaxis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:05:54
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Cholecystectomy prophylaxis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:05:16

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Gastritis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:05:00
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (antacid) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Gastritis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:03:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:22:46
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' answered with 'from SAE' (Site from DM).	Morgan Mathis (b) (4)	03 Nov 2020 20:23:37
User entered 'ANTIACID (From SAE)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	03 Nov 2020 20:23:25
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:05:53
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:14:57

PRODUCTION RELEASE (v12.003
EAB) (1725)

2306 of 2525

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User entered 'Antacid'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '40'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'twice daily (BID)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '02 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '05 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User entered '2'	System	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User entered '1'	System	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:40
User entered '804 (804)'	System	14 Oct 2020 18:54:34

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 18:43:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 18:43:21
Data point term sent to Coder	System	28 Jan 2021 13:53:58
Coding entries removed.	Ayssa Valente (b) (4)	28 Jan 2021 13:53:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 03:50:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 03:50:48
Data point term sent to Coder	System	14 Dec 2020 14:06:53
Coding entries removed.	Erin Harrelson (b) (4)	14 Dec 2020 14:06:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:10:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:10:19
Data point term sent to Coder	System	03 Nov 2020 20:24:59

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Morgan Mathis (b) (4)	03 Nov 2020 20:24:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 22:30:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 22:30:26
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 18:58:49
User entered 'METHOCARBAMOL'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication and prophylaxis field as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:09:20
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication and prophylaxis field as appropriate. ' answered with 'updated indication' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	28 Jan 2021 13:53:58
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication and prophylaxis field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:07:38
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'AE #2 [CHOLECYSTITIS]' reason for change: Data Entry Error	Ayssa Valente (b) (4)	28 Jan 2021 13:53:47
User closed query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (muscle relaxer) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Pain prophylaxis secondary to Cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 19:13:37
Query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (muscle relaxer) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Pain prophylaxis secondary to Cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4)	14 Dec 2020 14:06:23
DataPoint Un-verified.	(b) (4)	14 Dec 2020 14:06:16
User entered 'Pain prophylaxis secondary to Cholecystitis (FROM SAE)' reason for change: Data Entry Error	Erin Harrelson (b) (4)	14 Dec 2020 14:06:16
User opened query 'Per DM CLR-RQ: Response noted. However, drug's mechanism of action such as (muscle relaxer) is not permitted as indication per guidelines. Please provide underlying condition that this medication was used for (e.g. Pain prophylaxis secondary to Cholecystitis etc.). Ensure that the indication is reconciled with AE eCRF or prophylaxis is indicated. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:56

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:22:53
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' answered with 'from SAE' (Site from DM).	Morgan Mathis (b) (4)	03 Nov 2020 20:24:29
User entered 'MUSCLE RELAXER (from SAE)' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 20:24:08
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:06:01
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:15:08
User entered 'MUSCLE RELAXER'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '500'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:58:18
DataPoint Un-verified.	Morgan Mathis (b) (4)	20 Nov 2020 16:49:03
User entered 'four times daily (QID)' reason for change: Data Entry Error	(b) (4) Morgan Mathis (b) (4)	20 Nov 2020 16:49:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '3 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '5 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User entered '4'	System	20 Nov 2020 16:49:03
User entered '1'	System	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User entered '1'	System	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:43
User entered '804 (804)'	System	14 Oct 2020 18:58:03

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 14:54:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:54:19
Data point term sent to Coder	System	03 Nov 2020 20:21:53
Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 20:21:17
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:28:23
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 Oct 2020 22:28:23
Data point term sent to Coder	System	14 Oct 2020 18:59:51
User entered 'LORAZEPAM'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:08:56
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:22:58
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' answered with 'MEDICATION IS USED FOR ANXIETY' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:21:30
User entered 'ANXIOLYTIC (ANXIETY)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:21:17
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:06:07
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:02:37
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:15:17
User entered 'ANXIOLYTIC'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '.5'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '4 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered '4 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User entered empty.	System	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User entered empty.	System	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:17:58
User entered empty.	System	14 Oct 2020 18:59:00

US3082081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:03:57

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:22:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:09:17
User entered 'Yes (Y)'	Brandy Lowman (b) (4)	12 Oct 2020 12:34:57

US3082081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:01
User entered '3 Oct 2020'	Brandy Lowman (b) (4)	12 Oct 2020 12:38:46

US3082081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:01
User entered 'Cholecystectomy'	Brandy Lowman (b) (4)	12 Oct 2020 12:38:46

US3082081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:01
User entered 'Adverse Event (AE)'	Brandy Lowman (b) (4)	12 Oct 2020 12:38:46

US3082081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:57

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:01
User entered empty.	Brandy Lowman (b) (4)	12 Oct 2020 12:38:46

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'USA-US114-2020-MRNA-1273-P301000004'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Barton'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Williams'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Wilmington'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'NC'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '28403'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'US'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User entered '8'	System	30 Nov 2020 15:02:41
User entered '7'	System	18 Nov 2020 16:25:43
User entered '6'	System	30 Oct 2020 19:54:33
User entered '5'	System	15 Oct 2020 13:20:20
User entered '4'	System	14 Oct 2020 12:46:22
User entered '3'	System	13 Oct 2020 13:12:57
User entered '2'	System	07 Oct 2020 14:42:27
User entered '1'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'USA-US114-2020-MRNA-1273-P301000004'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Barton'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Williams'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Wilmington'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'NC'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '28403'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'US'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User entered '8'	System	30 Nov 2020 15:02:41
User entered '7'	System	18 Nov 2020 16:25:43
User entered '6'	System	30 Oct 2020 19:54:33
User entered '5'	System	15 Oct 2020 13:20:20
User entered '4'	System	14 Oct 2020 12:46:22
User entered '3'	System	13 Oct 2020 13:12:57
User entered '2'	System	07 Oct 2020 14:42:27
User entered '1'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
User entered '06/Oct/2020 14:36'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:57

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.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'USA-US114-2020-MRNA-1273-P301000004'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Barton'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Williams'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Wilmington'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'NC'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '28403'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'US'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User entered '8'	System	30 Nov 2020 15:02:41
User entered '7'	System	18 Nov 2020 16:25:43
User entered '6'	System	30 Oct 2020 19:54:33
User entered '5'	System	15 Oct 2020 13:20:20
User entered '4'	System	14 Oct 2020 12:46:22
User entered '3'	System	13 Oct 2020 13:12:57
User entered '2'	System	07 Oct 2020 14:42:27
User entered '1'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
User entered '07/Oct/2020 14:42'	System	07 Oct 2020 14:42:27

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:57

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.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:12:43
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 14:42:27

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered		
'USA-US114-2020-MRNA-1273-P301000004'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Barton'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Williams'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Wilmington'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'NC'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '28403'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'US'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User entered '8'	System	30 Nov 2020 15:02:41
User entered '7'	System	18 Nov 2020 16:25:43
User entered '6'	System	30 Oct 2020 19:54:33
User entered '5'	System	15 Oct 2020 13:20:20
User entered '4'	System	14 Oct 2020 12:46:22
User entered '3'	System	13 Oct 2020 13:12:57
User entered '2'	System	07 Oct 2020 14:42:27
User entered '1'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:03:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
User entered '13/Oct/2020 09:12'	System	13 Oct 2020 13:12:57

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:03:57

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.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:46:13
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 13:12:57

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered		
'USA-US114-2020-MRNA-1273-P301000004'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Barton'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Williams'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Wilmington'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'NC'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '28403'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'US'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User entered '8'	System	30 Nov 2020 15:02:41
User entered '7'	System	18 Nov 2020 16:25:43
User entered '6'	System	30 Oct 2020 19:54:33
User entered '5'	System	15 Oct 2020 13:20:20
User entered '4'	System	14 Oct 2020 12:46:22
User entered '3'	System	13 Oct 2020 13:12:57
User entered '2'	System	07 Oct 2020 14:42:27
User entered '1'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:03:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
User entered '14/Oct/2020 08:46'	System	14 Oct 2020 12:46:22

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:03:57

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.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:20:11
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 12:46:22

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered		
'USA-US114-2020-MRNA-1273-P301000004'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Barton'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Williams'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Wilmington'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'NC'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '28403'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'US'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User entered '8'	System	30 Nov 2020 15:02:41
User entered '7'	System	18 Nov 2020 16:25:43
User entered '6'	System	30 Oct 2020 19:54:33
User entered '5'	System	15 Oct 2020 13:20:20
User entered '4'	System	14 Oct 2020 12:46:22
User entered '3'	System	13 Oct 2020 13:12:57
User entered '2'	System	07 Oct 2020 14:42:27
User entered '1'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:03:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
User entered '15/Oct/2020 09:20'	System	15 Oct 2020 13:20:20

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:03:57

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.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 19:54:15
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 13:20:20

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'USA-US114-2020-MRNA-1273-P301000004'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Barton'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Williams'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Wilmington'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'NC'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '28403'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'US'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User entered '8'	System	30 Nov 2020 15:02:41
User entered '7'	System	18 Nov 2020 16:25:43
User entered '6'	System	30 Oct 2020 19:54:33
User entered '5'	System	15 Oct 2020 13:20:20
User entered '4'	System	14 Oct 2020 12:46:22
User entered '3'	System	13 Oct 2020 13:12:57
User entered '2'	System	07 Oct 2020 14:42:27
User entered '1'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:03:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
User entered '30/Oct/2020 15:54'	System	30 Oct 2020 19:54:33

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:03:57

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.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:25:27
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:08:52
User entered 'I'	(b) (4), (b) (6)	30 Oct 2020 19:54:33

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'USA-US114-2020-MRNA-1273-P301000004'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Barton'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Williams'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Wilmington'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'NC'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '28403'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'US'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User entered '8'	System	30 Nov 2020 15:02:41
User entered '7'	System	18 Nov 2020 16:25:43
User entered '6'	System	30 Oct 2020 19:54:33
User entered '5'	System	15 Oct 2020 13:20:20
User entered '4'	System	14 Oct 2020 12:46:22
User entered '3'	System	13 Oct 2020 13:12:57
User entered '2'	System	07 Oct 2020 14:42:27
User entered '1'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:03:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:56:52
User entered '18/Nov/2020 16:25'	System	18 Nov 2020 16:25:43

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:03:57

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.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 15:02:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:56:52
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 16:25:43

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'USA-US114-2020-MRNA-1273-P301000004'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

Serious

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'No (N)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Yes (Y)'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Barton'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Williams'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '3806 Peachtree Ave.'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'Wilmington'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered 'NC'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 14:36:06
User entered '28403'	System	06 Oct 2020 14:35:40

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:52
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:42:14
User entered 'US'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
	(b) (4)	
User entered '8'	System	30 Nov 2020 15:02:41
User entered '7'	System	18 Nov 2020 16:25:43
User entered '6'	System	30 Oct 2020 19:54:33
User entered '5'	System	15 Oct 2020 13:20:20
User entered '4'	System	14 Oct 2020 12:46:22
User entered '3'	System	13 Oct 2020 13:12:57
User entered '2'	System	07 Oct 2020 14:42:27
User entered '1'	System	06 Oct 2020 14:36:16

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:03:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:41:24
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered '30/Nov/2020 10:02'	(b) (4) System	30 Nov 2020 15:02:41

US3082081

Folder: SAE USA-US114-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:03:57

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)	16 Apr 2021 03:41:24
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 17:48:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 15:02:41