

US3722034 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:31:41

All time stamps listed in this document are displayed in GMT

US3722034

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

[Participant ID](#)

US3722034

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

US3722034

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:14:01

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 11:14:01

Generated On: 10 Jun 2021 09:31:41

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
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

US3722034

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Mar 2021 11:14:01

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3722034

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Mar 2021 11:14:01

Generated On: 10 Jun 2021 09:31:41

Were any significant conditions reported?

Yes ☒

No ☐

US3722034

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3722034

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN JUL 2020
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)	2 NOV 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	NOV 2020
Stop Year (derived)	2020

US3722034

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Condition	GYNECOMASTIA, MALE
Start date (dd MMM yyyy)	UN FEB 2017
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 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2017
Start Year (derived)	2017
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

US3722034

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Condition	DEGENERATIVE DISC DISEASE WORSE AT L4-L5
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3722034

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Condition	BILATERAL ORCHIECTOMY FOR SURGICAL CASTRATION DUE TO PROSTATE CANCER
Start date (dd MMM yyyy)	UN FEB 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2017
Start Year (derived)	2017
Stop Month and Year (derived)	FEB 2017
Stop Year (derived)	2017

US3722034

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:14:01

Generated On: 10 Jun 2021 09:31:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:38 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 12:38
Height (<i>xxx.x</i>)	143 cm
Weight (<i>xxx.x</i>)	233.8 lb
BMI (<i>xxx.x</i>)	51.96965 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722034

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:14:01

Generated On: 10 Jun 2021 09:31:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 AUG 2020

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

US3722034

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:14:01

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:14:01

Generated On: 10 Jun 2021 09:31:41

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	

US3722034

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

What was the date of randomization? (dd MMM yyyy) 02 AUG 2020

What was the participant's randomization number? 184393

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 ☒

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Height	ND - Not Done
Weight	ND - Not Done

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

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)	2 AUG 2020
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 12:36
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	2 AUG 2020
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 14:04
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

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.

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

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) 2 AUG 2020

What was the treatment time? (00:00-23:59) 13:34 (24 HR)

Treatment Date and Time (derived) 2 AUG 2020 13:34

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

What was the frequency of the study treatment dosing? ONCE

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

US3722034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 AUG 2020
Collection time (00:00-23:59)	13:00 (24 HR)
Collection date and time (derived)	2 AUG 2020 13:00

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Collection date (dd MMM yyyy)			2 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:01	2 AUG 2020 13:01
Nasopharyngeal Swab 2	Yes	13:01	2 AUG 2020 13:01

US3722034

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 02 AUG 2020 14:12

PC Open Date & Time 02 AUG 2020 13:54

PC Close Date & Time 02 AUG 2020 16:24

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	02 AUG 2020 17:24
PC Open Date & Time	02 AUG 2020 17:19
PC Close Date & Time	03 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

03 AUG 2020 13:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 16:09

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 AUG 2020 16:18

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 13:03

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:35

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 15:59

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

02 AUG 2020 14:13

PC Open Date & Time

02 AUG 2020 13:54

PC Close Date & Time

02 AUG 2020 16:24

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 17:24

PC Open Date & Time

02 AUG 2020 17:19

PC Close Date & Time

03 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 13:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

04 AUG 2020 16:10

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

05 AUG 2020 16:18

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

06 AUG 2020 13:04

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

07 AUG 2020 12:35

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

08 AUG 2020 15:59

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 14:14
PC Open Date & Time	02 AUG 2020 13:54
PC Close Date & Time	02 AUG 2020 16:24

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 17:25
PC Open Date & Time	02 AUG 2020 17:19
PC Close Date & Time	03 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

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 ☒

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 13:57
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

51 of 2817

EAB) (1725)

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 16:11
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

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 ☒

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 16:19
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 2817

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 13:04
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

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)

57 of 2817

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 12:36
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2817

EAB) (1725)

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 16:00
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:55:23

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:55:23

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:55:23

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:55:23

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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	VISIT2

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

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)	31 AUG 2020
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 09:52
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

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)	31 AUG 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:35
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 11:05 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 11:05

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

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

10:48 (24 HR)

Collection date and time (derived)

31 AUG 2020 10:48

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:11	31 AUG 2020 10:11
Nasopharyngeal Swab 2	Yes	10:11	31 AUG 2020 10:11

US3722034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 11:39

PC Open Date & Time

31 AUG 2020 11:25

PC Close Date & Time

31 AUG 2020 13:55

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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	31 AUG 2020 18:44
PC Open Date & Time	31 AUG 2020 14:50
PC Close Date & Time	01 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 17:12

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

98.8 °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

02 SEP 2020 12:42

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:13

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 15:44

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 07:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 16:46

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

31 AUG 2020 11:39

PC Open Date & Time

31 AUG 2020 11:25

PC Close Date & Time

31 AUG 2020 13:55

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 18:45

PC Open Date & Time

31 AUG 2020 14:50

PC Close Date & Time

01 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 17:13

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

02 SEP 2020 12:43

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

03 SEP 2020 14:13

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

04 SEP 2020 15:44

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

06 SEP 2020 07:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

06 SEP 2020 16:47

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 11:40
PC Open Date & Time	31 AUG 2020 11:25
PC Close Date & Time	31 AUG 2020 13:55

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 18:45
PC Open Date & Time	31 AUG 2020 14:50
PC Close Date & Time	01 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

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 ☒

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 17:13
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

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)

97 of 2817

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:43
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

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 ☒

PRODUCTION RELEASE (v12.003

99 of 2817

EAB) (1725)

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 14:14
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

101 of 2817

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 15:45
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

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)

103 of 2817

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 07:43
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

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 ☒

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 16:47
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:55:23

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:55:23

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 OCT 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 14:01
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

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

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	14:35 (24 HR)
Collection date and time (derived)	5 OCT 2020 14:35

US3722034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:55:24

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 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"/>

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 OCT 2020 00:01

Patient Cloud Close Date & Time

06 OCT 2020 23:59

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

11 OCT 2020 13:46:21

Patient Cloud Open Date & Time

09 OCT 2020 00:01

Patient Cloud Close Date & Time

13 OCT 2020 23:59

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

20 OCT 2020 11:13:51

Patient Cloud Open Date & Time

16 OCT 2020 00:01

Patient Cloud Close Date & Time

20 OCT 2020 23:59

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 NOV 2020 09:16:16
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 11:24:38

Patient Cloud Open Date & Time

06 NOV 2020 00:01

Patient Cloud Close Date & Time

10 NOV 2020 23:59

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 10:58:48

Patient Cloud Open Date & Time

13 NOV 2020 00:01

Patient Cloud Close Date & Time

17 NOV 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 NOV 2020 10:13:17
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

28 NOV 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

04 DEC 2020 15:34:56

Patient Cloud Open Date & Time

01 DEC 2020 00:01

Patient Cloud Close Date & Time

05 DEC 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

12 DEC 2020 10:44:46

Patient Cloud Open Date & Time

08 DEC 2020 00:01

Patient Cloud Close Date & Time

12 DEC 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

15 DEC 2020 08:57:15

Patient Cloud Open Date & Time

15 DEC 2020 00:01

Patient Cloud Close Date & Time

19 DEC 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

22 DEC 2020 08:11:11

Patient Cloud Open Date & Time

22 DEC 2020 00:01

Patient Cloud Close Date & Time

26 DEC 2020 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

29 DEC 2020 08:26:39

Patient Cloud Open Date & Time

29 DEC 2020 00:01

Patient Cloud Close Date & Time

02 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

05 JAN 2021 06:50:25

Patient Cloud Open Date & Time

05 JAN 2021 00:01

Patient Cloud Close Date & Time

09 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

12 JAN 2021 15:56:34

Patient Cloud Open Date & Time

12 JAN 2021 00:01

Patient Cloud Close Date & Time

16 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

21 JAN 2021 14:46:08

Patient Cloud Open Date & Time

19 JAN 2021 00:01

Patient Cloud Close Date & Time

23 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 13:20:03

Patient Cloud Open Date & Time

26 JAN 2021 00:01

Patient Cloud Close Date & Time

30 JAN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

02 FEB 2021 08:58:19

Patient Cloud Open Date & Time

02 FEB 2021 00:01

Patient Cloud Close Date & Time

06 FEB 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 08:57:35

Patient Cloud Open Date & Time

09 FEB 2021 00:01

Patient Cloud Close Date & Time

13 FEB 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 13:59:33

Patient Cloud Open Date & Time

16 FEB 2021 00:01

Patient Cloud Close Date & Time

20 FEB 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 12:50:09

Patient Cloud Open Date & Time

23 FEB 2021 00:01

Patient Cloud Close Date & Time

27 FEB 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

02 MAR 2021 07:42:17

Patient Cloud Open Date & Time

02 MAR 2021 00:01

Patient Cloud Close Date & Time

06 MAR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

09 MAR 2021 06:18:52

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 08:27:28

Patient Cloud Open Date & Time

16 MAR 2021 00:01

Patient Cloud Close Date & Time

20 MAR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

23 MAR 2021 13:48:51

Patient Cloud Open Date & Time

23 MAR 2021 00:01

Patient Cloud Close Date & Time

27 MAR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

31 MAR 2021 12:33:30

Patient Cloud Open Date & Time

30 MAR 2021 00:01

Patient Cloud Close Date & Time

03 APR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

06 APR 2021 11:53:12

Patient Cloud Open Date & Time

06 APR 2021 00:01

Patient Cloud Close Date & Time

10 APR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

14 APR 2021 14:44:21

Patient Cloud Open Date & Time

13 APR 2021 00:01

Patient Cloud Close Date & Time

17 APR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 06:20:29

Patient Cloud Open Date & Time

20 APR 2021 00:01

Patient Cloud Close Date & Time

24 APR 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 10:00:28

Patient Cloud Open Date & Time

27 APR 2021 00:01

Patient Cloud Close Date & Time

01 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 327

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

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

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

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

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

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

29 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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="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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

17 JUL 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

31 JUL 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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°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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	21 SEP 2021 00:01
Patient Cloud Close Date & Time	25 SEP 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

09 OCT 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 <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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	21 DEC 2021 00:01
Patient Cloud Close Date & Time	25 DEC 2021 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

29 JAN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

19 FEB 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

26 FEB 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

19 MAR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

29 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

23 APR 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 670

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

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

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

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

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

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

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

21 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	16 JUL 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

23 JUL 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐ Yes ☐

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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"/>

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:12:44

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:12:44

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:48:00

Generated On: 10 Jun 2021 09:31:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:48:00

Generated On: 10 Jun 2021 09:31:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 MAR 2021
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 13:05
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:48:00

Generated On: 10 Jun 2021 09:31:41

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.

US3722034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00-23:59)	13:12 (24 HR)
Collection date and time (derived)	9 MAR 2021 13:12

US3722034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722034

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:31:41

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"/>

US3722034

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:31:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3722034

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3722034

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Date of updated informed consent (<i>dd MMM yyyy</i>)	09 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	09 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3722034

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Height	
Weight	
BMI (xxx.x)	

US3722034

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 JAN 2021
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	09 JAN 2021 10:35
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 JAN 2021
Time of assessment (00:00-23:59)	11:11 (24 HR)
Vital Signs Date and Time (derived)	09 JAN 2021 11:11
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 JAN 2021

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

US3722034

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 10:41 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 10:41

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

US3722034

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	9 JAN 2021
-------------------------------	------------

Collection time (00:00-23:59)	11:00 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	9 JAN 2021 11:00
------------------------------------	------------------

US3722034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 JAN 2021
Collection time (00:00 - 23:59)	11:03
Collection Date and Time (derived)	9 JAN 2021 11:03

US3722034

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:47:54

Generated On: 10 Jun 2021 09:31:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:47:54

Generated On: 10 Jun 2021 09:31:41

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 FEB 2021
Time of assessment (00:00-23:59)	13:19 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 13:19
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:47:54

Generated On: 10 Jun 2021 09:31:41

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 15:58
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3722034

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:47:54

Generated On: 10 Jun 2021 09:31:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3722034

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:47:54

Generated On: 10 Jun 2021 09:31:41

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 13:28 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 13:28

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

US3722034

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:54

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3722034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722034

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 APR 2021
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 08:40
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722034

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

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.

US3722034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:47:55

Generated On: 10 Jun 2021 09:31:41

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 APR 2021
Collection time (00:00-23:59)	08:45 (24 HR)
Collection date and time (derived)	5 APR 2021 08:45

US3722034

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:31:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

AEID USA-US083-2020-MRNA-1273-P30
1000001

Adverse event METASTATIC CASTRATE
SENSITIVE PROSTRATE
CANCER WITH METASTASES

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) 01 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) 24 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☐
Grade 3/Severe ☒
Grade 4 ☐

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

347 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
<hr/>		
Persistent or significant disability or incapacity		False
<hr/>		
Congenital anomaly or birth defect		False
<hr/>		
Other medically important event		True
<hr/>		
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Other action taken (check all that apply)		
<hr/>		
None		False
<hr/>		
Concomitant Medication		True
<hr/>		
Concomitant Procedure		True
<hr/>		
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input type="radio"/>
	Recovered/Resolved with Sequelae	<input checked="" type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	INCREASED PAIN, OSSEOUS METASTASES, MULTIPLE BONY LYTIC LESIONS, T9 AND T12 FOR PAIN MANAGEMENT	
<hr/>		
Narrative		

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

SUBJECT HAD MEDICAL
HISTORY OF PROSTATE
CANCER DIAGNOSED IN 2017.
SUBJECT REPORTED
WORSENING OF BACK PAIN
09SEP2020. SUBJECT
PRESENTED TODAY FOR DAY
57 AND REPORTED WORSENING
OF PROSTATE CANCER.
MEDICAL RECORD RELEASE
OBTAINED AND SITE WILL
UPDATE ONCE RECORDS ARE
RECEIVED AND REVIEWED.
COLONOSCOPY SHOWED
METAPLASTIC POLYPS
XRAY OF ABDOMEN SHOWED
MULTILEVEL LUMBAR
SPONDYLOSIS
CERVICAL XRAY SHOWED
POSSIBLE C4 FRACTURE OR
LYTIC CHANGES AS WELL AS
PLEURAL CHANGES.

IMAGING FROM 11-4-2020: CT
CHEST - SHOWS MULTIPLE
LYTIC LESIONS WITHIN THE
BONES; CT OF ABDOMEN AND
PELVIS: RETROPERITONEAL
AND BILATERAL PELVIC
ADENOPATHY CONCERNING
FOR METASTATIC LESIONS.
MANY DEMONSTRATE
HETEROGENEOUS AREAS OF

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

DECREASED ATTENUATION
SUGGESTING NECROSIS;
NUCLEAR MEDICINE BONE
SCAN - NO SCINTIGRAPHIC
EVIDENCE OF OSSEOUS
METASTASES.

IMAGING FROM 9-18-2020: CT
CHEST: MULTIPLE LYTIC
LESIONS PRESENT WITHIN THE
BONES CONCERNING FOR
MULTIPLE MYELOMA OR
METASTASIS, NO SIGNIFICANT
PLEURAL OR PARENCHYMAL
ABNORMALITY. CT CERVICAL
SPINE: LYTIC CERVICAL SPINE
LESIONS CONCERNING FOR
MULTIPLE MYELOMA OR
METASTASIS FROM UNKNOWN
PRIMARY NEOPLASM. THE
LESIONS ARE NOT SCLEROTIC
AS TYPICALLY SEEN IN
METASTATIC PROSTATE
CANCER, SUSPECTED
AGE-INDETERMINATE
COMPRESSION FRACTURE AT
C4.

ABDOMINAL CT ON 19 OCT 2020
REPORTED NO SIGNIFICANT
ABNORMALITIES.

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)	

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

AEID	
Adverse event	LOW IRON
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)	4 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

AEID	
Adverse event	NECK PAIN
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)	1 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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)

353 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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)	

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

AEID	
Adverse event	INTERMITTENT CONSTIPATION
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 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

AEID

Adverse event

WORSENING OF INSOMNIA

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)

01 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)

02 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

357 of 2817

EAB) (1725)

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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)	_____

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

AEID

Adverse event

METAPLASTIC POLYPS IN
COLON

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)

01 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)

1 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

359 of 2817

EAB) (1725)

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

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	False
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	POLYPS REMOVED DURING COLONOSCOPY
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)	

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

AEID	
Adverse event	DEGENERATIVE DISC DISEASE WORSE AT L4-L5
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)	1 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	X-RAY OF THE ABDOMEN PERFORMED ON 01SEP2020 REVEALED MULTILEVEL LUMBAR SPONDYLOSIS
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)	
PRODUCTION RELEASE (v12.003)	
EAB) (1725)	362 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

AEID	
Adverse event	ANXIETY
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)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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)

363 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

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 type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

AEID	
Adverse event	POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES
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)	1 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
CT OF CHEST DONE FOR STAGING OF CANCER AND FINDINGS WERE REPORTED IN SAE NARRATIVE AND AE ADDED IN RESPONSE TO QUERY.	
Serious Adverse Event Derived (CSA Programming Field Only)	0

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 21:47:51

Generated On: 10 Jun 2021 09:31:41

Persistent or significant disability or incapacity	
Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Relationship to Study Procedure	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Action taken with investigational product	None <input type="checkbox"/>
	Dose Delayed <input type="checkbox"/>
	Investigational Product <input type="checkbox"/>
	Withdrawn <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal <input type="checkbox"/>
	Not Recovered/Not Resolved <input type="checkbox"/>
	Recovered/Resolved <input type="checkbox"/>
	Recovered/Resolved with Sequelae <input type="checkbox"/>
	Recovering/Resolving <input type="checkbox"/>
	Unknown <input type="checkbox"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	
Medically Attended AE Derived (CSA Programming Field Only)	
Admitted to ICU Derived (CSA Programming Field Only)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:47:54

Generated On: 10 Jun 2021 09:31:41

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

Yes ☒

No ☐

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

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication HIP PAIN

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

371 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication XTANDI

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 160

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 2019
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication METASTATIC CASTRATE
SENSITIVE PROSTRATE
CANCER WITH METASTASES

Dose per administration 7.5-325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

375 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN RELATED TO
METASTATIC CASTRATE
SENSITIVE PROSTRATE
CANCER WITH METASTASES

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION/GENERALIZED PAIN

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN 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)		UN SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication 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

EAB) (1725)

385 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication LACTATED RINGERS INFUSION

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF PROSTATE
CANCER

Dose per administration 100

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	IV	
Start date (dd MMM yyyy)	29 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 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"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication SODIUM CHLORIDE FLUSH

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 5-40

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

EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003

389 of 2817

EAB) (1725)

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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)	29 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 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"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication SODIUM CHLORIDE FLUSH

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 5-40

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

391 of 2817

EAB) (1725)

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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)	29 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 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"/>	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication HYDROMORPHONE (PF)

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

393 of 2817

EAB) (1725)

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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)	29 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 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"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication ROMAZICON

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 0.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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)	29 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 NOV 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>	
	No <input 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"/>	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication PHENERGAN

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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)	29 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 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"/>	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

399 of 2817

EAB) (1725)

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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)	29 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 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"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication MARCAINE

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

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

401 of 2817

EAB) (1725)

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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)	29 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 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"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication PORCINE (HEPARIN)

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

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

403 of 2817

EAB) (1725)

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	INTERCATHETER	
Start date (dd MMM yyyy)	29 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 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"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

405 of 2817

EAB) (1725)

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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 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"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication CARBOPLATIN

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

407 of 2817

EAB) (1725)

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication ETOPOSIDE

Prophylaxis Yes ☐
No ☒

Indication PROSTATE CANCER

Dose per administration UNK

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)

409 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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 NOV 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 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"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication ISOVUL 370

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL AND PELVIC CT

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)

411 of 2817

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	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 checked="" type="checkbox"/>
If route of administration is Other, specify		IV
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 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"/>

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

Name of Medication DECACRON

Prophylaxis Yes ☐
No ☒

Indication POST CHEMO FATIGUE

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

413 of 2817

EAB) (1725)

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:47:53

Generated On: 10 Jun 2021 09:31:41

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:47:54

Generated On: 10 Jun 2021 09:31:41

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 21:47:54

Generated On: 10 Jun 2021 09:31:41

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 SEP 2020	COLONOSCOPY WITH POLYPS REMOVAL	Adverse Event	
1 SEP 2020	X-RAY OF THE ABDOMEN	Adverse Event	
3 SEP 2020	CERVICAL XRAY	Adverse Event	
18 SEP 2020	CT CHEST WITH CONTRAST	Adverse Event	
19 OCT 2020	CT OF ABDOMEN	Adverse Event	
19 OCT 2020	NUCLEAR MEDICINE BONE SCAN	Adverse Event	
4 NOV 2020	CT ABDOMEN AND PELVIS	Adverse Event	

US3722034

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:31:41

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

US3722034

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:31:41

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 ☐

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	06/OCT/2020 13:41
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

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/NOV/2020 21:11
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

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	13/JAN/2021 16:07
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

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/FEB/2021 10:15
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

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:37
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

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/MAR/2021 06:24
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

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/APR/2021 13:12
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

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/APR/2021 13:10
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

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 21:47:56

Generated On: 10 Jun 2021 09:31:41

SAEID	USA-US083-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	LUIS
Investigator's Last Name	DE LA CRUZ
Site Address: Street	2 ROPER CORNERS CIR
Site Address: City	GREENVILLE
Site Address: State	SC
Site Address: Postal Code	29615
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	19/APR/2021 13:44
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

US3722034 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722034

Form: Participant Creation

Generated On: 10 Jun 2021 09:31:41

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:55:41
User entered 'US3722034'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 16:24:06

US3722034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 17:51:45

US3722034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '02 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 16:24:07

US3722034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'Clinic (Clinic)'	Amy Ford (b) (4)	02 Aug 2020 17:51:45

US3722034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'SCRN'	System	02 Aug 2020 17:51:45

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 16:24:07

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	02 Aug 2020 17:52:55
User entered '65' reason for change: Data Entry Error	Amy Ford (b) (4)	02 Aug 2020 17:52:55
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	02 Aug 2020 17:52:35
User entered '62'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'YEARS'	System	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '65'	System	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'Male (M)'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'I'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:31:41

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:52:35

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '2 Aug 2020'	Amy Ford (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Aug 2020'	System	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2020'	System	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:52:14
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:29:30
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:29:26
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:56:40
User entered 'Amendment 5 (5)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:53:59

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 16:24:07

US3722034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:31:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'I'	System	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per Medical records received for SAE, subject had bilateral orchiectomy for surgical castration in 2017. Please update Medical History.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:28:43
Query 'Per Medical records received for SAE, subject had bilateral orchiectomy for surgical castration in 2017. Please update Medical History.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 18:48:55
User opened query 'Per Medical records received for SAE, subject had bilateral orchiectomy for surgical castration in 2017. Please update Medical History.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 19:55:51
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:31:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
Query 'Medical Records obtained for SAE indicate subject reports of neck pain, low back pain (unspecified laterality), and urinary frequency. Please verify and update EDC as appropriate.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:04:14
User opened query 'Medical Records obtained for SAE indicate subject reports of neck pain, low back pain (unspecified laterality), and urinary frequency. Please verify and update EDC as appropriate.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:52:00
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:32:46

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:38:58
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 16:34:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 16:34:01
Data point term sent to Coder	System	05 Aug 2020 16:33:38
User entered 'Prostate cancer'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:03
User entered 'UN UNK 2017'	Kayla Peay (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:05
User entered '0'	Kayla Peay (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:09
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:17
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:39:20
User entered '0'	Kayla Peay (b) (4)	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Jan 2017'	System	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2017'	System	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	05 Aug 2020 16:33:07

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:29:04
User closed query 'Please confirm laterality of hip pain, as medical records received for SAE indicate history of Right hip pain.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:29:02
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 19:13:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 19:13:27
Data point term sent to Coder	System	03 Feb 2021 19:13:09
Query 'Please confirm laterality of hip pain, as medical records received for SAE indicate history of Right hip pain.' answered with 'EDC Updated per SAE medical records' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 19:12:55
Coding entries removed.	(b) (4), (b) (6)	03 Feb 2021 19:12:16
User entered 'RIGHT HIP PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 19:12:16
User opened query 'Please confirm laterality of hip pain, as medical records received for SAE indicate history of Right hip pain.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:46:46
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 17:45:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:07
User closed query 'Per DM CLR: Please specify the laterality of HIP PAIN (Left, Right or Bilateral). Review and update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:32:52

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 20:14:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 20:14:26
Query 'Per DM CLR: Please specify the laterality of HIP PAIN (Left, Right or Bilateral). Review and update Med History eCRF as appropriate.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 20:13:03
' answered with 'UPDATED' (Site from DM).		
Data point term sent to Coder	System	05 Oct 2020 20:13:03
Coding entries removed.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 20:12:44
User entered 'BILATERAL HIP PAIN' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	05 Oct 2020 20:12:44
User opened query 'Per DM CLR: Please specify the laterality of HIP PAIN (Left, Right or Bilateral). Review and update Med History eCRF as appropriate.	(b) (4), (b) (6)	25 Sep 2020 11:25:42
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 02:01:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 02:01:39
Data point term sent to Coder	System	10 Aug 2020 02:00:42
User entered 'HIP PAIN'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:13
User entered 'UN Jul 2020'	Amy Ford (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:15
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:16
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:18
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:19
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Jul 2020'	System	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2020'	System	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	10 Aug 2020 02:00:06

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:41:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:02:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:02:43
Data point term sent to Coder	System	10 Nov 2020 22:01:49
User entered 'Diverticulitis'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:37
User entered 'UN Jun 2020'	Amy Ford (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:42
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:40
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:43
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:41:45
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Jun 2020'	System	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2020'	System	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	10 Nov 2020 22:00:57

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:29:48
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:24:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:24:42
Data point term sent to Coder	System	10 Nov 2020 22:23:24
User entered 'INSOMNIA'	Amy Ford (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'UN Jul 2020'	Amy Ford (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User closed query 'Please verify end date, as an AE of worsening of insomnia with a start date of 01Sep20 is noted in AEs.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:29:17
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
Query 'Please verify end date, as an AE of worsening of insomnia with a start date of 01Sep20 is noted in AEs.' answered with 'This was completed and updated in AE ' (Site from CRA).	Sara Poff (b) (4)	24 Feb 2021 19:16:34
User opened query 'Please verify end date, as an AE of worsening of insomnia with a start date of 01Sep20 is noted in AEs.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:06:32
User entered '2 Nov 2020'	Amy Ford (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Jul 2020'	System	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2020'	System	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Nov 2020'	System	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2020'	System	10 Nov 2020 22:22:59

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:42:08
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast disorders NEC, PT: Gynaecomastia, LLT: Gynaecomastia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:23:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:23:48
Data point term sent to Coder	System	11 Nov 2020 01:35:50
User entered 'Gynaecomastia, male'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:42:09
User entered 'UN Feb 2017'	Amy Ford (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:42:11
User entered '0'	Amy Ford (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User closed query 'Please verify if this condition remains ongoing. Medical records received for SAE appear to indicate the presence of severe bilateral gynecomastia at 18Sep20 office visit.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:29:36
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
Query 'Please verify if this condition remains ongoing. Medical records received for SAE appear to indicate the presence of severe bilateral gynecomastia at 18Sep20 office visit.' answered with 'Still ongoing ' (Site from CRA).	Sara Poff (b) (4)	24 Feb 2021 19:17:00
User opened query 'Please verify if this condition remains ongoing. Medical records received for SAE appear to indicate the presence of severe bilateral gynecomastia at 18Sep20 office visit.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 19:27:04
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 19:25:26
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:42:12
User entered 'No (N)'	Amy Ford (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 19:25:27
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:42:14
User entered 'UN Oct 2020'	Amy Ford (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:42:16
User entered '0'	Amy Ford (b) (4)	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Feb 2017'	System	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2017'	System	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Oct 2020'	System	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2020'	System	11 Nov 2020 01:35:03

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:31:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Lumbar disc degeneration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:18:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:18:45
Data point term sent to Coder	System	11 Nov 2020 01:35:50
User entered 'Degenerative Disc Disease worse at L4-L5'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:31:28
User entered 'UN UNK 2019'	Amy Ford (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:31:28
User entered '0'	Amy Ford (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:31:28
User entered 'Yes (Y)'	Amy Ford (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:31:28
User entered empty.	Amy Ford (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:31:28
User entered '0'	Amy Ford (b) (4)	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Jan 2019'	System	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2019'	System	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	11 Nov 2020 01:35:39

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Testicular and scrotal therapeutic procedures, PT: Orchidectomy, LLT: Orchiectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:20:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 10:20:41
User signature succeeded.	Luis De La Cruz (b) (4) (b) (4)	09 Mar 2021 11:14:01
Data point term sent to Coder	System	03 Mar 2021 18:52:17
User entered 'Bilateral orchiectomy for surgical castration due to prostate cancer'	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'un Feb 2017'	Marlee Smith (b) (4)	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Marlee Smith (b) (4)	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:48:43
Query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 17:07:11
Signature has been broken.	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 17:07:06
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	23 Mar 2021 17:07:06
User opened query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 08:10:11
User signature succeeded.	Luis De La Cruz (b) (4) (b) (4)	09 Mar 2021 11:14:01
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Signature has been broken.	Marlee Smith (b) (4)	23 Mar 2021 17:07:06
User entered 'un Feb 2017' reason for change: Data Entry Error	Marlee Smith (b) (4)	23 Mar 2021 17:07:06
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered empty.	Marlee Smith (b) (4)	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Marlee Smith (b) (4)	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Feb 2017'	System	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2017'	System	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Feb 2017'	System	23 Mar 2021 17:07:06
User entered empty.	System	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2017'	System	23 Mar 2021 17:07:06
User entered empty.	System	03 Mar 2021 18:51:19

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Fear symptoms and phobic disorders (incl social phobia), PT: Claustrophobia, LLT: Claustrophobia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 14:54:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 14:54:36
Data point term sent to Coder	System	20 Apr 2021 14:53:28
User entered 'Claustrophobia'	Marlee Smith (b) (4)	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'un UNK 2017'	Marlee Smith (b) (4)	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	Marlee Smith (b) (4)	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '0'	Marlee Smith (b) (4)	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'Jan 2017'	System	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2017'	System	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered empty.	System	20 Apr 2021 14:53:11

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '2 Aug 2020'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '12:38'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered '2 Aug 2020 12:38'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '143' cm	Kayla Peay (b) (4)	05 Aug 2020 16:34:15
DataPoint set to visible.	System	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '233.8' lb reason for change: Data Entry Error	(b) (4)	07 Aug 2020 17:19:14
User entered '106' kg	Kayla Peay (b) (4)	05 Aug 2020 16:34:15
DataPoint set to visible.	(b) (4) System	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
Amendment Manager: User entered '51.96965'	System	16 Sep 2020 23:40:44
User entered '52.0'	System	07 Aug 2020 17:19:14
User entered '51.8'	System	05 Aug 2020 16:34:15
DataPoint set to visible.	System	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'kg/m2'	System	05 Aug 2020 16:34:15
DataPoint set to visible.	System	02 Aug 2020 17:54:16

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 13:43:28
User entered '97.8' F	Kayla Peay (b) (4)	05 Aug 2020 16:34:15
	(b) (4)	

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:28
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 13:43:28
User entered '73'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15
	(b) (4)	

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'bpm'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 13:43:28
User entered '17'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15
	(b) (4)	

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'breaths/min'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 13:43:28
User entered '134'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15
	(b) (4)	

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'mmHg'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 13:43:28
User entered '85'	Kayla Peay (b) (4)	05 Aug 2020 16:34:15
	(b) (4)	

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User entered 'mmHg'	System	05 Aug 2020 16:34:15

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44

US3722034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44

US3722034

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:21

US3722034

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 14:07:40
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 15:17:10
User entered '2 Aug 2020'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:21

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

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)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered 'I'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:31:41

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:44
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:14:01
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 17:55:27

US3722034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 17:55:58

US3722034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '2 Aug 2020'	Amy Ford (b) (4)	02 Aug 2020 17:55:58

US3722034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Clinic (Clinic)'	Amy Ford (b) (4)	02 Aug 2020 17:55:58

US3722034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'VISIT1'	System	02 Aug 2020 17:55:58

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '02 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 17:29:05

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:41

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:40:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:40:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Aug 2020 17:29:05
User entered '184393' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 17:29:05

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:41

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 17:29:05

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:41

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)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:41

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)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:41

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:41

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:31:41

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 17:57:35

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '143' cm reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '233.8' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '143' cm reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '233.8' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '2 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '12:36' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '2 Aug 2020 12:36'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '97.8' F reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '73' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'bpm'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '17' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'breaths/min'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '134' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'mmHg'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '85' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'mmHg'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '143' cm reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:39
User entered '233.8' lb reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '2 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 12:16:13
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 13:30:19
User entered '14:04' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '2 Aug 2020 14:04'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '97.3' F reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '74' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'bpm'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '17' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'breaths/min'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '136' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'mmHg'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '84' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:30:19
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'mmHg'	System	11 Aug 2020 13:30:19
User entered empty.	System	05 Aug 2020 16:34:50

US3722034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:28:24
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 16:34:54

US3722034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 13:43:47
User entered '2 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:28:24
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 16:34:54

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

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 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'MRNA-1273 OR PLACEBO'	System	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '2 Aug 2020'	Amy Ford (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '13:34'	Amy Ford (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '2 Aug 2020 13:34'	System	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Left Arm (LEFT ARM)'	Amy Ford (b) (4)	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'ONCE'	System	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'INTRAMUSCULAR'	System	02 Aug 2020 17:58:05

US3722034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 16:35:13

US3722034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '2 Aug 2020'	Kayla Peay (b) (4)	05 Aug 2020 16:35:13

US3722034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '13:00'	Kayla Peay (b) (4)	05 Aug 2020 16:35:13

US3722034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '2 Aug 2020 13:00'	System	05 Aug 2020 16:35:13

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:31:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '2 Aug 2020'	Kayla Peay (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '13:01'	Kayla Peay (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '2 Aug 2020 13:01'	System	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '13:01'	Kayla Peay (b) (4)	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '2 Aug 2020 13:01'	System	05 Aug 2020 16:35:34

US3722034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 16:35:38

US3722034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	05 Aug 2020 16:35:38

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:11:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered 'Yes (Y)'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered '97.3'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered 'Yes (Y)'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered '0'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'CONFIRM' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 06:31:14
User opened query 'Per the participant response, medication was taken to prevent 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).	Amy Ford (b) (4)	09 Aug 2020 18:32:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	(b) (4)	
User entered '1'	System	02 Aug 2020 18:13:01
	System	02 Aug 2020 18:13:01
	System	02 Aug 2020 18:13:01
	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:12:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bb97ce13-bf3e-4455-8c80-c6536f80afaa'	System	02 Aug 2020 18:13:01
User entered '02 Aug 2020 14:12'	System	02 Aug 2020 18:13:01

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Aug 2020 13:54'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Aug 2020 16:24'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:23:37', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e8454058-6690-4445-a016-7597ed78117d'	System	02 Aug 2020 21:24:06
User entered 'Yes (Y)'	System	02 Aug 2020 21:24:06

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:23:47', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e8454058-6690-4445-a016-7597ed78117d'	System	02 Aug 2020 21:24:06
User entered '98.2'	System	02 Aug 2020 21:24:06

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:23:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e8454058-6690-4445-a016-7597ed78117d'	System	02 Aug 2020 21:24:06
User entered 'No (N)'	System	02 Aug 2020 21:24:06

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:02', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e8454058-6690-4445-a016-7597ed78117d'	System	02 Aug 2020 21:24:06
User entered '02 Aug 2020 17:24'	System	02 Aug 2020 21:24:06

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Aug 2020 17:19'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 2'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:55:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '77317f7b-836e-40df-85e7-b885590fe334'	System	03 Aug 2020 17:56:08
User entered 'Yes (Y)'	System	03 Aug 2020 17:56:08

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:55:52', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '77317f7b-836e-40df-85e7-b885590fe334'	System	03 Aug 2020 17:56:08
User entered '98.2'	System	03 Aug 2020 17:56:08

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:55:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '77317f7b-836e-40df-85e7-b885590fe334'	System	03 Aug 2020 17:56:08
User entered 'No (N)'	System	03 Aug 2020 17:56:08

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '77317f7b-836e-40df-85e7-b885590fe334'	System	03 Aug 2020 17:56:08
User entered '03 Aug 2020 13:56'	System	03 Aug 2020 17:56:08

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 3'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:09:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '55b649c3-ffd5-4f70-9a3a-c090509da029'	System	04 Aug 2020 20:09:58
User entered 'Yes (Y)'	System	04 Aug 2020 20:09:58

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:09:45', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '55b649c3-ffd5-4f70-9a3a-c090509da029' User entered '97.6'	System	04 Aug 2020 20:09:58
	System	04 Aug 2020 20:09:58

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:09:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '55b649c3-ffd5-4f70-9a3a-c090509da029'	System	04 Aug 2020 20:09:58
User entered 'No (N)'	System	04 Aug 2020 20:09:58

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:09:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '55b649c3-ffd5-4f70-9a3a-c090509da029'	System	04 Aug 2020 20:09:58
User entered '04 Aug 2020 16:09'	System	04 Aug 2020 20:09:58

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 4'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:17:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered 'Yes (Y)'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:17:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered '98.4'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:17:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered 'Yes (Y)'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONFIRM' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 06:35:22
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).	Amy Ford (b) (4)	09 Aug 2020 18:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	(b) (4)	
User entered '1'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered '0'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '790b1859-dcb3-4023-8a92-44583d8bf0cc'	System	05 Aug 2020 20:18:15
User entered '05 Aug 2020 16:18'	System	05 Aug 2020 20:18:15

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 5'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:18', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '08e8ddad-5810-4489-8423-df4becf417aa'	System	06 Aug 2020 17:03:40
User entered 'Yes (Y)'	System	06 Aug 2020 17:03:40

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '08e8ddad-5810-4489-8423-df4becf417aa'	System	06 Aug 2020 17:03:40
User entered '97.8'	System	06 Aug 2020 17:03:40

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '08e8ddad-5810-4489-8423-df4becf417aa'	System	06 Aug 2020 17:03:40
User entered 'No (N)'	System	06 Aug 2020 17:03:40

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '08e8ddad-5810-4489-8423-df4becf417aa'	System	06 Aug 2020 17:03:40
User entered '06 Aug 2020 13:03'	System	06 Aug 2020 17:03:40

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 6'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:10', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e293da09-4293-4123-919c-08e36af3db79'	System	07 Aug 2020 16:35:35
User entered 'Yes (Y)'	System	07 Aug 2020 16:35:35

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:22', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e293da09-4293-4123-919c-08e36af3db79'	System	07 Aug 2020 16:35:35
User entered '98.2'	System	07 Aug 2020 16:35:35

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e293da09-4293-4123-919c-08e36af3db79'	System	07 Aug 2020 16:35:35
User entered 'No (N)'	System	07 Aug 2020 16:35:35

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:33', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e293da09-4293-4123-919c-08e36af3db79'	System	07 Aug 2020 16:35:35
User entered '07 Aug 2020 12:35'	System	07 Aug 2020 16:35:35

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 7'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:58:47', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f57579b0-d0b4-4e05-a910-113f6a6c55a0'	System	08 Aug 2020 19:59:12
User entered 'Yes (Y)'	System	08 Aug 2020 19:59:12

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:58:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f57579b0-d0b4-4e05-a910-113f6a6c55a0'	System	08 Aug 2020 19:59:12
User entered '98.0'	System	08 Aug 2020 19:59:12

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f57579b0-d0b4-4e05-a910-113f6a6c55a0'	System	08 Aug 2020 19:59:12
User entered 'No (N)'	System	08 Aug 2020 19:59:12

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f57579b0-d0b4-4e05-a910-113f6a6c55a0'	System	08 Aug 2020 19:59:12
User entered '08 Aug 2020 15:59'	System	08 Aug 2020 19:59:12

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:13:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered 'None (1)'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:13:32', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered 'No (N)'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:13:36', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered 'No (N)'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:13:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered 'None (1)'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:13:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3dd9a292-e94f-4443-9aaa-5d98a7fa7418'	System	02 Aug 2020 18:13:57
User entered '02 Aug 2020 14:13'	System	02 Aug 2020 18:13:57

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Aug 2020 13:54'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Aug 2020 16:24'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered 'None (1)'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered 'No (N)'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered 'No (N)'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered 'None (1)'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:48', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '425a0a6a-9edd-437b-adf3-eacf834b295b'	System	02 Aug 2020 21:24:50
User entered '02 Aug 2020 17:24'	System	02 Aug 2020 21:24:50

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Aug 2020 17:19'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 2'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered 'None (1)'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered 'No (N)'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered 'No (N)'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered 'None (1)'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4713b51f-8d8b-40fe-8be0-ac1fadb9f10b'	System	03 Aug 2020 17:56:37
User entered '03 Aug 2020 13:56'	System	03 Aug 2020 17:56:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 3'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered 'None (1)'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered 'No (N)'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:14', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered 'No (N)'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered 'None (1)'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '594f4b57-b845-4595-a93b-7924b3e61257'	System	04 Aug 2020 20:10:26
User entered '04 Aug 2020 16:10'	System	04 Aug 2020 20:10:26

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 4'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:18', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered 'None (1)'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:22', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered 'No (N)'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered 'No (N)'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered 'None (1)'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:36', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ce64e10f-a966-4832-892c-86f4e8242a6c'	System	05 Aug 2020 20:18:36
User entered '05 Aug 2020 16:18'	System	05 Aug 2020 20:18:36

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 5'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:45', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebca0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered 'None (1)'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebea0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered 'No (N)'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebea0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered 'No (N)'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:03:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebca0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered 'None (1)'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '46aebea0-582c-4152-9336-5df2f637ac03'	System	06 Aug 2020 17:04:05
User entered '06 Aug 2020 13:04'	System	06 Aug 2020 17:04:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 6'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered 'None (1)'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered 'No (N)'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered 'No (N)'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered 'None (1)'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:35:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'aebb0f16-0baf-4e30-a054-3e8732fdb6be'	System	07 Aug 2020 16:36:03
User entered '07 Aug 2020 12:35'	System	07 Aug 2020 16:36:03

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 7'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered 'None (1)'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered 'No (N)'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered 'No (N)'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered 'None (1)'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9e57960d-1894-4058-9288-6a686385dc42'	System	08 Aug 2020 19:59:37
User entered '08 Aug 2020 15:59'	System	08 Aug 2020 19:59:37

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:33', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'None (0)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered 'No (N)'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T14:14:44', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '96005fd1-2e9c-4545-9362-e65cfea6c604'	System	02 Aug 2020 18:14:49
User entered '02 Aug 2020 14:14'	System	02 Aug 2020 18:14:49

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Aug 2020 13:54'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Aug 2020 16:24'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:24:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a' User entered 'None (0)'	System	02 Aug 2020 21:25:45
	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'None (0)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered 'No (N)'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-02T17:25:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa42036c-9c83-4584-bafc-ac2ffdd30a1a'	System	02 Aug 2020 21:25:45
User entered '02 Aug 2020 17:25'	System	02 Aug 2020 21:25:45

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Aug 2020 17:19'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 2'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:45', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:56:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:57:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'None (0)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:57:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered 'No (N)'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-03T13:57:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '48108877-c7a1-419b-b5a9-d3cb80a70223'	System	03 Aug 2020 17:57:16
User entered '03 Aug 2020 13:57'	System	03 Aug 2020 17:57:16

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 3'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:41', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:10:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'Some interference with activity (2)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:11:02', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:11:07', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:11:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'None (0)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:11:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered 'No (N)'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-04T16:11:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'db2f2bd4-83cd-4d51-b2ae-25691b4071a8'	System	04 Aug 2020 20:11:36
User entered '04 Aug 2020 16:11'	System	04 Aug 2020 20:11:36

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 4'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:44', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681' User entered 'None (0)'	System	05 Aug 2020 20:19:32
	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:18:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'None (0)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered 'No (N)'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-05T16:19:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd80d83fe-05b4-47ee-8cb3-965781680681'	System	05 Aug 2020 20:19:32
User entered '05 Aug 2020 16:19'	System	05 Aug 2020 20:19:32

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 5'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:37', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'None (0)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered 'No (N)'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-06T13:04:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39286dd5-d9bb-4062-9b88-33ecc96a35d4'	System	06 Aug 2020 17:04:59
User entered '06 Aug 2020 13:04'	System	06 Aug 2020 17:04:59

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 6'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:15', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda' User entered 'None (0)'	System	07 Aug 2020 16:36:37
	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:18', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'None (0)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered 'No (N)'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-07T12:36:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'fa4aa370-0902-4078-b90e-f85c312b3cda'	System	07 Aug 2020 16:36:37
User entered '07 Aug 2020 12:36'	System	07 Aug 2020 16:36:37

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 7'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T15:59:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'None (0)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T16:00:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered 'No (N)'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-08T16:00:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd7888cc0-9021-4f7d-89bc-d8e30783aae7'	System	08 Aug 2020 20:00:06
User entered '08 Aug 2020 16:00'	System	08 Aug 2020 20:00:06

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 17:58:05

US3722034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	10 Aug 2020 00:56:10
User entered 'Yes (Y)'	System	10 Aug 2020 00:55:55
	Amy Ford (b) (4)	10 Aug 2020 00:55:55
	(b) (4)	

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '09 Aug 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	10 Nov 2020 22:20:01
User entered '9 Aug 2020' reason for change: Data Entry Error	Amy Ford (b) (4)	10 Aug 2020 00:56:10
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:55:55

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	10 Aug 2020 00:55:55

US3722034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:55:55

US3722034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Aug 2020 00:56:18

US3722034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	10 Aug 2020 00:56:18

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Amy Ford (b) (4)	16 Aug 2020 19:09:51

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '16 Aug 2020'	Amy Ford (b) (4)	16 Aug 2020 19:09:51

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	16 Aug 2020 19:09:51

US3722034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Amy Ford (b) (4)	16 Aug 2020 19:09:51

US3722034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Amy Ford (b) (4)	16 Aug 2020 19:09:39

US3722034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	16 Aug 2020 19:09:39

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	27 Aug 2020 12:50:59

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '26 Aug 2020'	Kayla Peay (b) (4)	27 Aug 2020 12:50:59

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	27 Aug 2020 12:50:59

US3722034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Kayla Peay (b) (4)	27 Aug 2020 12:50:59

US3722034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	27 Aug 2020 12:50:37

US3722034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	27 Aug 2020 12:50:37

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Sara Poff (b) (4)	31 Aug 2020 15:17:10

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '31 Aug 2020'	Sara Poff (b) (4)	31 Aug 2020 15:17:10

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	31 Aug 2020 15:17:10

US3722034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'VISIT2'	System	31 Aug 2020 15:17:10

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '31 Aug 2020'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '09:52'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '31 Aug 2020 09:52'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '97.1' F	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '70'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'bpm'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '20'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'breaths/min'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '113'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'mmHg'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '77'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'mmHg'	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '31 Aug 2020'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '11:35' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '31 Aug 2020 11:35'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '98.4' F reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41
	(b) (4)	

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '62' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41
	(b) (4)	

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'bpm'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '17' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'breaths/min'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '137' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41
	(b) (4)	

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'mmHg'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 18:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 18:58:45
User entered '86' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 18:58:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 15:20:41
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 15:20:41
	(b) (4)	

US3722034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'mmHg'	System	31 Aug 2020 18:58:45
User entered empty.	System	31 Aug 2020 15:20:41

US3722034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 15:20:48

US3722034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '31 Aug 2020'	Kayla Peay (b) (4)	31 Aug 2020 15:20:48

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Sara Poff (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Sara Poff (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

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 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Sara Poff (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '31 Aug 2020'	Sara Poff (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '11:05'	Sara Poff (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '31 Aug 2020 11:05'	System	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'ONCE'	System	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 15:17:39

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 15:21:00

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '31 Aug 2020'	Kayla Peay (b) (4)	31 Aug 2020 15:21:00

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '10:48'	Kayla Peay (b) (4)	31 Aug 2020 15:21:00

US3722034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '31 Aug 2020 10:48'	System	31 Aug 2020 15:21:00

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:31:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '31 Aug 2020'	Kayla Peay (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '10:11'	Kayla Peay (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '31 Aug 2020 10:11'	System	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:41

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '10:11'	Kayla Peay (b) (4)	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered '31 Aug 2020 10:11'	System	31 Aug 2020 15:21:14

US3722034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Sara Poff (b) (4)	31 Aug 2020 15:17:47

US3722034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	31 Aug 2020 15:17:47

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:38:39', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f1fa89a6-5cd0-4118-83a8-40303da8832b'	System	31 Aug 2020 15:47:49
User entered 'Yes (Y)'	System	31 Aug 2020 15:47:49

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:38:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f1fa89a6-5cd0-4118-83a8-40303da8832b' User entered '98.4'	System	31 Aug 2020 15:47:49
	System	31 Aug 2020 15:47:49

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f1fa89a6-5cd0-4118-83a8-40303da8832b'	System	31 Aug 2020 15:47:49
User entered 'No (N)'	System	31 Aug 2020 15:47:49

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'f1fa89a6-5cd0-4118-83a8-40303da8832b'	System	31 Aug 2020 15:47:49
User entered '31 Aug 2020 11:39'	System	31 Aug 2020 15:47:49

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '31 Aug 2020 11:25'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '31 Aug 2020 13:55'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:44:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cf48a6b0-69ea-4d15-8c5a-34eaac6d7238'	System	31 Aug 2020 22:44:54
User entered 'Yes (Y)'	System	31 Aug 2020 22:44:54

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:44:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cf48a6b0-69ea-4d15-8c5a-34eaac6d7238'	System	31 Aug 2020 22:44:54
User entered '98.7'	System	31 Aug 2020 22:44:54

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:44:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cf48a6b0-69ea-4d15-8c5a-34eaac6d7238'	System	31 Aug 2020 22:44:54
User entered 'No (N)'	System	31 Aug 2020 22:44:54

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:44:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cf48a6b0-69ea-4d15-8c5a-34eaac6d7238'	System	31 Aug 2020 22:44:54
User entered '31 Aug 2020 18:44'	System	31 Aug 2020 22:44:54

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '31 Aug 2020 14:50'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 2'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:15', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'lead28e5-9b4d-481b-a45b-4f8d638af202'	System	01 Sep 2020 21:12:39
User entered 'Yes (Y)'	System	01 Sep 2020 21:12:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'lead28e5-9b4d-481b-a45b-4f8d638af202'	System	01 Sep 2020 21:12:39
User entered '98.7'	System	01 Sep 2020 21:12:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'lead28e5-9b4d-481b-a45b-4f8d638af202'	System	01 Sep 2020 21:12:39
User entered 'No (N)'	System	01 Sep 2020 21:12:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'lead28e5-9b4d-481b-a45b-4f8d638af202'	System	01 Sep 2020 21:12:39
User entered '01 Sep 2020 17:12'	System	01 Sep 2020 21:12:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 3'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:41:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3149c421-e814-46fa-8029-53037ef37375'	System	02 Sep 2020 16:42:25
User entered 'Yes (Y)'	System	02 Sep 2020 16:42:25

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3149c421-e814-46fa-8029-53037ef37375' User entered '98.8'	System	02 Sep 2020 16:42:25
	System	02 Sep 2020 16:42:25

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:18', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3149c421-e814-46fa-8029-53037ef37375'	System	02 Sep 2020 16:42:25
User entered 'No (N)'	System	02 Sep 2020 16:42:25

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3149c421-e814-46fa-8029-53037ef37375'	System	02 Sep 2020 16:42:25
User entered '02 Sep 2020 12:42'	System	02 Sep 2020 16:42:25

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 4'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39a25c4f-9480-42c2-b54a-d283c8f6854c'	System	03 Sep 2020 18:13:27
User entered 'Yes (Y)'	System	03 Sep 2020 18:13:27

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39a25c4f-9480-42c2-b54a-d283c8f6854c' User entered '96.6'	System	03 Sep 2020 18:13:27
	System	03 Sep 2020 18:13:27

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39a25c4f-9480-42c2-b54a-d283c8f6854c'	System	03 Sep 2020 18:13:27
User entered 'No (N)'	System	03 Sep 2020 18:13:27

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '39a25c4f-9480-42c2-b54a-d283c8f6854c'	System	03 Sep 2020 18:13:27
User entered '03 Sep 2020 14:13'	System	03 Sep 2020 18:13:27

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 5'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:43:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3ee7e733-886e-444d-aac8-3c1b55b54e95'	System	04 Sep 2020 19:44:20
User entered 'Yes (Y)'	System	04 Sep 2020 19:44:20

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3ee7e733-886e-444d-aac8-3c1b55b54e95'	System	04 Sep 2020 19:44:20
User entered '97.6'	System	04 Sep 2020 19:44:20

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:07', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3ee7e733-886e-444d-aac8-3c1b55b54e95'	System	04 Sep 2020 19:44:20
User entered 'No (N)'	System	04 Sep 2020 19:44:20

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3ee7e733-886e-444d-aac8-3c1b55b54e95'	System	04 Sep 2020 19:44:20
User entered '04 Sep 2020 15:44'	System	04 Sep 2020 19:44:20

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 6'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:41:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '5408e36b-6548-4373-97f7-d2cdd9ef041c'	System	06 Sep 2020 11:42:17
User entered 'Yes (Y)'	System	06 Sep 2020 11:42:17

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:41:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '5408e36b-6548-4373-97f7-d2cdd9ef041c' User entered '97.6'	System	06 Sep 2020 11:42:17
	System	06 Sep 2020 11:42:17

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '5408e36b-6548-4373-97f7-d2cdd9ef041c'	System	06 Sep 2020 11:42:17
User entered 'No (N)'	System	06 Sep 2020 11:42:17

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:07', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '5408e36b-6548-4373-97f7-d2cdd9ef041c' User entered '06 Sep 2020 07:42'	System	06 Sep 2020 11:42:17
	System	06 Sep 2020 11:42:17

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 7'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:46:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6eb45fb-1eaf-4175-9e38-0df60cd8c526'	System	06 Sep 2020 20:47:03
User entered 'Yes (Y)'	System	06 Sep 2020 20:47:03

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:46:50', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6eb45fb-1eaf-4175-9e38-0df60cd8c526'	System	06 Sep 2020 20:47:03
User entered '97.6'	System	06 Sep 2020 20:47:03

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:46:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6eb45fb-1eaf-4175-9e38-0df60cd8c526'	System	06 Sep 2020 20:47:03
User entered 'No (N)'	System	06 Sep 2020 20:47:03

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:46:59', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6eb45fb-1eaf-4175-9e38-0df60cd8c526'	System	06 Sep 2020 20:47:03
User entered '06 Sep 2020 16:46'	System	06 Sep 2020 20:47:03

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered 'None (1)'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:33', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered 'No (N)'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered 'No (N)'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered 'None (1)'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '38d4be73-a0b8-4a2a-9f50-0053344ed9d6'	System	31 Aug 2020 15:48:00
User entered '31 Aug 2020 11:39'	System	31 Aug 2020 15:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '31 Aug 2020 11:25'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '31 Aug 2020 13:55'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:44:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered 'None (1)'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered 'No (N)'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered 'No (N)'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:14', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered 'None (1)'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9ca4eb62-e195-47e9-b15a-1da0fa2fc3a9'	System	31 Aug 2020 22:45:24
User entered '31 Aug 2020 18:45'	System	31 Aug 2020 22:45:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '31 Aug 2020 14:50'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 2'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered 'None (1)'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:12:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered 'No (N)'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered 'No (N)'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered 'None (1)'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '7616512e-858d-4257-aed4-b4de746081b6'	System	01 Sep 2020 21:13:13
User entered '01 Sep 2020 17:13'	System	01 Sep 2020 21:13:13

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 3'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered 'None (1)'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:39', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered 'No (N)'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:42:44', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered 'No (N)'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered 'None (1)'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e6591f35-d858-4998-aeca-2012739a50f0'	System	02 Sep 2020 16:43:12
User entered '02 Sep 2020 12:43'	System	02 Sep 2020 16:43:12

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 4'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered 'None (1)'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered 'No (N)'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered 'No (N)'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered 'None (1)'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:44', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '63ed841e-0c86-4883-aa4b-96097f1d2a77'	System	03 Sep 2020 18:13:49
User entered '03 Sep 2020 14:13'	System	03 Sep 2020 18:13:49

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 5'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered 'None (1)'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:27', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered 'No (N)'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered 'No (N)'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered 'None (1)'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'b3015244-ab7f-4c40-8b61-c2939e7bcb9e'	System	04 Sep 2020 19:44:42
User entered '04 Sep 2020 15:44'	System	04 Sep 2020 19:44:42

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 6'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered 'None (1)'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered 'No (N)'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered 'No (N)'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered 'None (1)'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4208b4ca-ad6c-49ea-bbe7-fd0715a9aaa4'	System	06 Sep 2020 11:42:38
User entered '06 Sep 2020 07:42'	System	06 Sep 2020 11:42:38

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 7'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered 'None (1)'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered 'No (N)'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered 'No (N)'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered 'None (1)'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c078a101-b924-4906-89f9-25654c41ef78'	System	06 Sep 2020 20:47:24
User entered '06 Sep 2020 16:47'	System	06 Sep 2020 20:47:24

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:39:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'None (0)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered 'No (N)'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T11:40:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd5cd2e35-eb18-4dc2-9945-7d97f3f5523d'	System	31 Aug 2020 15:47:58
User entered '31 Aug 2020 11:40'	System	31 Aug 2020 15:47:58

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '31 Aug 2020 11:25'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '31 Aug 2020 13:55'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359' User entered 'None (0)'	System	31 Aug 2020 22:45:59
	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'None (0)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered 'No (N)'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-08-31T18:45:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'cbb51111-4ecb-4759-8fb9-d122c5e84359'	System	31 Aug 2020 22:45:59
User entered '31 Aug 2020 18:45'	System	31 Aug 2020 22:45:59

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '31 Aug 2020 14:50'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 2'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:14', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:20', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:26', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'None (0)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:37', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered 'No (N)'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-01T17:13:41', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a25a4728-d6a1-4d66-8883-a807eca9bee3'	System	01 Sep 2020 21:13:46
User entered '01 Sep 2020 17:13'	System	01 Sep 2020 21:13:46

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 3'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:15', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:22', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'None (0)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4'	System	02 Sep 2020 16:43:42
User entered 'No (N)'	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-02T12:43:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6391de8f-82ba-48df-a491-a34f0328b4e4' User entered '02 Sep 2020 12:43'	System	02 Sep 2020 16:43:42
	System	02 Sep 2020 16:43:42

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 4'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:13:54', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'None (0)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:24', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered 'No (N)'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-03T14:14:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3f0847b5-6ff2-4ba8-a893-b1131016d905'	System	03 Sep 2020 18:14:34
User entered '03 Sep 2020 14:14'	System	03 Sep 2020 18:14:34

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 5'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:48', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d' User entered 'None (0)'	System	04 Sep 2020 19:45:19
	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d' User entered 'None (0)'	System	04 Sep 2020 19:45:19
	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d' User entered 'None (0)'	System	04 Sep 2020 19:45:19
	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:44:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d' User entered 'None (0)'	System	04 Sep 2020 19:45:19
	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:45:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d' User entered 'None (0)'	System	04 Sep 2020 19:45:19
	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:45:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d' User entered 'None (0)'	System	04 Sep 2020 19:45:19
	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:45:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d'	System	04 Sep 2020 19:45:19
User entered 'No (N)'	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-04T15:45:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '954b1ac7-0829-4cb4-9161-674d774ba16d' User entered '04 Sep 2020 15:45'	System	04 Sep 2020 19:45:19
	System	04 Sep 2020 19:45:19

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 6'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:32', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1' User entered 'None (0)'	System	06 Sep 2020 11:43:14
	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'None (0)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:39', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'None (0)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1' User entered 'None (0)'	System	06 Sep 2020 11:43:14
	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1' User entered 'None (0)'	System	06 Sep 2020 11:43:14
	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:42:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'None (0)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:43:02', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered 'No (N)'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T07:43:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '368d4837-d1ce-4ae7-bf39-abb3a70b43d1'	System	06 Sep 2020 11:43:14
User entered '06 Sep 2020 07:43'	System	06 Sep 2020 11:43:14

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	31 Aug 2020 15:17:39
User entered 'Day 7'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:24', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:39', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:43', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:49', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'None (0)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:53', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered 'No (N)'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-09-06T16:47:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c19ed188-57ba-4745-8291-00146b5b075c'	System	06 Sep 2020 20:48:00
User entered '06 Sep 2020 16:47'	System	06 Sep 2020 20:48:00

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:17:39

US3722034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:17:39

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	16 Sep 2020 14:56:54

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '9 Sep 2020'	Kayla Peay (b) (4)	16 Sep 2020 14:56:54

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	16 Sep 2020 14:56:54

US3722034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Kayla Peay (b) (4)	16 Sep 2020 14:56:54

US3722034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	16 Sep 2020 14:56:57

US3722034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	16 Sep 2020 14:56:57

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Amy Ford (b) (4)	22 Sep 2020 20:04:06

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '17 Sep 2020'	Amy Ford (b) (4)	22 Sep 2020 20:04:06

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	22 Sep 2020 20:04:06

US3722034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Amy Ford (b) (4)	22 Sep 2020 20:04:06

US3722034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Amy Ford (b) (4)	22 Sep 2020 20:04:12

US3722034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	22 Sep 2020 20:04:12

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	23 Sep 2020 12:12:39

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '22 Sep 2020'	Kayla Peay (b) (4)	23 Sep 2020 12:12:39

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	23 Sep 2020 12:12:39

US3722034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Kayla Peay (b) (4)	23 Sep 2020 12:12:39

US3722034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	23 Sep 2020 12:12:43

US3722034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	23 Sep 2020 12:12:43

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 18:03:33

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '5 Oct 2020'	Kayla Peay (b) (4)	05 Oct 2020 18:03:33

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Clinic (Clinic)'	Kayla Peay (b) (4)	05 Oct 2020 18:03:33

US3722034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User entered 'VISIT3'	System	05 Oct 2020 18:03:33

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '5 Oct 2020'	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '14:01'	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User entered '5 Oct 2020 14:01'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '98.7' F	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered empty.	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '73'	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User entered 'bpm'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '18'	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User entered 'breaths/min'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '124'	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User entered 'mmHg'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '80'	Kayla Peay (b) (4)	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User entered 'mmHg'	System	05 Oct 2020 18:23:11

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31

US3722034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31

US3722034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 18:37:59

US3722034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '5 Oct 2020'	Kayla Peay (b) (4)	05 Oct 2020 18:37:59

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 18:39:52

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '5 Oct 2020'	Kayla Peay (b) (4)	05 Oct 2020 18:39:52

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered '14:35'	Kayla Peay (b) (4)	05 Oct 2020 18:39:52

US3722034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:31
User entered '5 Oct 2020 14:35'	System	05 Oct 2020 18:39:52

US3722034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:55:24
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Oct 2020 18:39:55

US3722034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	05 Oct 2020 18:39:55

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 64'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '02 Oct 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:42:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:32:35
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '06 Oct 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 71'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-10-11T13:46:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bffa922e-8288-4363-a5fa-1a797e7f1c63'	System	11 Oct 2020 17:46:27
User entered 'No (N)'	System	11 Oct 2020 17:46:27

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-10-11T13:46:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bffa922e-8288-4363-a5fa-1a797e7f1c63'	System	11 Oct 2020 17:46:27
User entered 'No (N)'	System	11 Oct 2020 17:46:27

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-10-11T13:46:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'bffa922e-8288-4363-a5fa-1a797e7f1c63'	System	11 Oct 2020 17:46:27
User entered '11 Oct 2020 13:46:21'	System	11 Oct 2020 17:46:27

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '09 Oct 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '13 Oct 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 78'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-10-20T11:13:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '42dcd55b-0c21-4b12-be04-37e50d630f26'	System	20 Oct 2020 15:13:55
User entered 'No (N)'	System	20 Oct 2020 15:13:55

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-10-20T11:13:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '42dcd55b-0c21-4b12-be04-37e50d630f26'	System	20 Oct 2020 15:13:55
User entered 'No (N)'	System	20 Oct 2020 15:13:55

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-10-20T11:13:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '42dcd55b-0c21-4b12-be04-37e50d630f26'	System	20 Oct 2020 15:13:55
User entered '20 Oct 2020 11:13:51'	System	20 Oct 2020 15:13:55

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '16 Oct 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '20 Oct 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 92'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-02T09:15:47', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered 'Yes (Y)'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-02T09:15:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered 'No (N)'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-02T09:16:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered 'No (N)'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-02T09:16:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered 'No (N)'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-02T09:16:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '99542cb9-df43-494a-955d-c1453e11bcb6'	System	02 Nov 2020 14:16:19
User entered '02 Nov 2020 09:16:16'	System	02 Nov 2020 14:16:19

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '30 Oct 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '03 Nov 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 99'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-09T11:24:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c832ec52-c90e-4b64-9329-2c618a37f594'	System	09 Nov 2020 16:24:44
User entered 'No (N)'	System	09 Nov 2020 16:24:44

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-09T11:24:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c832ec52-c90e-4b64-9329-2c618a37f594'	System	09 Nov 2020 16:24:44
User entered 'No (N)'	System	09 Nov 2020 16:24:44

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-09T11:24:38', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c832ec52-c90e-4b64-9329-2c618a37f594'	System	09 Nov 2020 16:24:44
User entered '09 Nov 2020 11:24:38'	System	09 Nov 2020 16:24:44

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '06 Nov 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '10 Nov 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered 'Day 106'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-17T10:58:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '71409c8b-ec2f-449c-b3a1-9b15b0c4b34f'	System	17 Nov 2020 15:58:51
User entered 'No (N)'	System	17 Nov 2020 15:58:51

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-17T10:58:37', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '71409c8b-ec2f-449c-b3a1-9b15b0c4b34f'	System	17 Nov 2020 15:58:51
User entered 'No (N)'	System	17 Nov 2020 15:58:51

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-17T10:58:48', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '71409c8b-ec2f-449c-b3a1-9b15b0c4b34f' User entered '17 Nov 2020 10:58:48'	System	17 Nov 2020 15:58:51
	System	17 Nov 2020 15:58:51

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '13 Nov 2020 00:01'	System	02 Aug 2020 17:58:05

US3722034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:34
Data entry locked.	System	02 Aug 2020 17:58:05
User entered '17 Nov 2020 23:59'	System	02 Aug 2020 17:58:05

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (8f005bd6459ce894)', Time: '2020-11-20T10:13:01', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '80f821f3-d2b1-480f-8bad-3d47270594e5'	System	20 Nov 2020 15:13:18
User entered 'No (N)'	System	20 Nov 2020 15:13:18

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (8f005bd6459ce894)', Time: '2020-11-20T10:13:05', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '80f821f3-d2b1-480f-8bad-3d47270594e5'	System	20 Nov 2020 15:13:18
User entered 'No (N)'	System	20 Nov 2020 15:13:18

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f005bd6459ce894)', Time: '2020-11-20T10:13:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '80f821f3-d2b1-480f-8bad-3d47270594e5'	System	20 Nov 2020 15:13:18
User entered '20 Nov 2020 10:13:17'	System	20 Nov 2020 15:13:18

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2020-12-04T15:34:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '57e23e5c-13a2-4ddc-9316-c950c471345e'	System	04 Dec 2020 20:34:55
User entered 'No (N)'	System	04 Dec 2020 20:34:55

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2020-12-04T15:34:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '57e23e5c-13a2-4ddc-9316-c950c471345e'	System	04 Dec 2020 20:34:55
User entered 'No (N)'	System	04 Dec 2020 20:34:55

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2020-12-04T15:34:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '57e23e5c-13a2-4ddc-9316-c950c471345e' User entered '04 Dec 2020 15:34:56'	System	04 Dec 2020 20:34:55
	System	04 Dec 2020 20:34:55

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2020-12-12T10:44:32', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ef510043-fef2-4cdc-aa52-7d3cc3edfc31'	System	12 Dec 2020 15:44:49
User entered 'No (N)'	System	12 Dec 2020 15:44:49

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2020-12-12T10:44:40', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ef510043-fef2-4cdc-aa52-7d3cc3edfc31'	System	12 Dec 2020 15:44:49
User entered 'No (N)'	System	12 Dec 2020 15:44:49

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2020-12-12T10:44:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'ef510043-fef2-4cdc-aa52-7d3cc3edfc31'	System	12 Dec 2020 15:44:49
User entered '12 Dec 2020 10:44:46'	System	12 Dec 2020 15:44:49

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2020-12-15T08:56:57', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3df93da6-d106-4dbc-ac84-d29756a7707f'	System	15 Dec 2020 13:57:17
User entered 'No (N)'	System	15 Dec 2020 13:57:17

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2020-12-15T08:57:07', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3df93da6-d106-4dbc-ac84-d29756a7707f'	System	15 Dec 2020 13:57:17
User entered 'No (N)'	System	15 Dec 2020 13:57:17

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2020-12-15T08:57:15', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3df93da6-d106-4dbc-ac84-d29756a7707f' User entered '15 Dec 2020 08:57:15'	System	15 Dec 2020 13:57:17
	System	15 Dec 2020 13:57:17

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2020-12-22T08:10:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4b35c67c-ffc1-4f69-a996-76299e938c4c'	System	22 Dec 2020 13:11:13
User entered 'No (N)'	System	22 Dec 2020 13:11:13

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2020-12-22T08:11:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4b35c67c-ffc1-4f69-a996-76299e938c4c'	System	22 Dec 2020 13:11:13
User entered 'No (N)'	System	22 Dec 2020 13:11:13

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2020-12-22T08:11:11', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4b35c67c-ffc1-4f69-a996-76299e938c4c'	System	22 Dec 2020 13:11:13
User entered '22 Dec 2020 08:11:11'	System	22 Dec 2020 13:11:13

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2020-12-29T08:26:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4cb7aea8-d9c2-41c6-9afa-96d8b2f7eba8'	System	29 Dec 2020 13:26:39
User entered 'No (N)'	System	29 Dec 2020 13:26:39

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2020-12-29T08:26:31', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4cb7aea8-d9c2-41c6-9afa-96d8b2f7eba8'	System	29 Dec 2020 13:26:39
User entered 'No (N)'	System	29 Dec 2020 13:26:39

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2020-12-29T08:26:39', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4cb7aea8-d9c2-41c6-9afa-96d8b2f7eba8' User entered '29 Dec 2020 08:26:39'	System	29 Dec 2020 13:26:39
	System	29 Dec 2020 13:26:39

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-01-05T06:50:04', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a6554cb1-48f8-4cc9-aff3-4123b82ccdfc'	System	05 Jan 2021 11:50:36
User entered 'No (N)'	System	05 Jan 2021 11:50:36

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-01-05T06:50:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a6554cb1-48f8-4cc9-aff3-4123b82ccdfe'	System	05 Jan 2021 11:50:36
User entered 'No (N)'	System	05 Jan 2021 11:50:36

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-01-05T06:50:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a6554cb1-48f8-4cc9-aff3-4123b82ccdfe'	System	05 Jan 2021 11:50:36
User entered '05 Jan 2021 06:50:25'	System	05 Jan 2021 11:50:36

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-01-12T15:56:22', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e0b1db9e-01f6-4baf-87bc-dfe548163df1'	System	12 Jan 2021 20:56:37
User entered 'No (N)'	System	12 Jan 2021 20:56:37

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-01-12T15:56:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e0b1db9e-01f6-4baf-87bc-dfe548163df1'	System	12 Jan 2021 20:56:37
User entered 'No (N)'	System	12 Jan 2021 20:56:37

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-01-12T15:56:34', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e0b1db9e-01f6-4baf-87bc-dfe548163df1' User entered '12 Jan 2021 15:56:34'	System	12 Jan 2021 20:56:37
	System	12 Jan 2021 20:56:37

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-01-21T14:45:56', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9f0efcb9-10a7-4876-89dd-b545a1f14b7d'	System	21 Jan 2021 19:46:06
User entered 'No (N)'	System	21 Jan 2021 19:46:06

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-01-21T14:46:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9f0efcb9-10a7-4876-89dd-b545a1f14b7d'	System	21 Jan 2021 19:46:06
User entered 'No (N)'	System	21 Jan 2021 19:46:06

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-01-21T14:46:08', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '9f0efcb9-10a7-4876-89dd-b545a1f14b7d' User entered '21 Jan 2021 14:46:08'	System	21 Jan 2021 19:46:06

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-01-28T13:19:55', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a54c32f0-456f-4c5d-bdee-53fef7e1db7c'	System	28 Jan 2021 18:20:07
User entered 'No (N)'	System	28 Jan 2021 18:20:07

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-01-28T13:20:00', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a54c32f0-456f-4c5d-bdee-53fef7e1db7c'	System	28 Jan 2021 18:20:07
User entered 'No (N)'	System	28 Jan 2021 18:20:07

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-01-28T13:20:03', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a54c32f0-456f-4c5d-bdee-53fef7e1db7c' User entered '28 Jan 2021 13:20:03'	System	28 Jan 2021 18:20:07
	System	28 Jan 2021 18:20:07

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-02-02T08:58:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '264180b9-8fca-4704-95ff-8fa08efbe95b'	System	02 Feb 2021 13:58:21
User entered 'No (N)'	System	02 Feb 2021 13:58:21

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-02-02T08:58:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '264180b9-8fca-4704-95ff-8fa08efbe95b'	System	02 Feb 2021 13:58:21
User entered 'No (N)'	System	02 Feb 2021 13:58:21

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-02-02T08:58:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '264180b9-8fca-4704-95ff-8fa08efbe95b'	System	02 Feb 2021 13:58:21
User entered '02 Feb 2021 08:58:19'	System	02 Feb 2021 13:58:21

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-02-09T08:57:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4428b7ac-0600-4a9d-82a0-80489b9d12de'	System	09 Feb 2021 13:57:37
User entered 'No (N)'	System	09 Feb 2021 13:57:37

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-02-09T08:57:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4428b7ac-0600-4a9d-82a0-80489b9d12de'	System	09 Feb 2021 13:57:37
User entered 'No (N)'	System	09 Feb 2021 13:57:37

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-02-09T08:57:35', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '4428b7ac-0600-4a9d-82a0-80489b9d12de'	System	09 Feb 2021 13:57:37
User entered '09 Feb 2021 08:57:35'	System	09 Feb 2021 13:57:37

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-02-16T13:59:16', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6fbc82d8-17f8-4755-a883-85770d5d6056'	System	16 Feb 2021 18:59:36
User entered 'No (N)'	System	16 Feb 2021 18:59:36

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-02-16T13:59:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6fbc82d8-17f8-4755-a883-85770d5d6056'	System	16 Feb 2021 18:59:36
User entered 'No (N)'	System	16 Feb 2021 18:59:36

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-02-16T13:59:33', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '6fbc82d8-17f8-4755-a883-85770d5d6056'	System	16 Feb 2021 18:59:36
User entered '16 Feb 2021 13:59:33'	System	16 Feb 2021 18:59:36

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-02-23T12:49:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e13238c9-f825-412c-8a79-4f34c6b8b3d2'	System	23 Feb 2021 17:50:13
User entered 'No (N)'	System	23 Feb 2021 17:50:13

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-02-23T12:50:02', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e13238c9-f825-412c-8a79-4f34c6b8b3d2'	System	23 Feb 2021 17:50:13
User entered 'No (N)'	System	23 Feb 2021 17:50:13

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-02-23T12:50:09', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e13238c9-f825-412c-8a79-4f34c6b8b3d2'	System	23 Feb 2021 17:50:13
User entered '23 Feb 2021 12:50:09'	System	23 Feb 2021 17:50:13

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-03-02T07:42:07', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a6e07c8c-c2dd-4064-a936-9f938f7b4f64'	System	02 Mar 2021 12:42:19
User entered 'No (N)'	System	02 Mar 2021 12:42:19

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-03-02T07:42:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a6e07c8c-c2dd-4064-a936-9f938f7b4f64'	System	02 Mar 2021 12:42:19
User entered 'No (N)'	System	02 Mar 2021 12:42:19

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-03-02T07:42:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a6e07c8c-c2dd-4064-a936-9f938f7b4f64'	System	02 Mar 2021 12:42:19
User entered '02 Mar 2021 07:42:17'	System	02 Mar 2021 12:42:19

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-03-09T06:18:42', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3bb38afd-e61b-409e-976e-063067392d6a'	System	09 Mar 2021 11:57:27
User entered 'No (N)'	System	09 Mar 2021 11:57:27

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-03-09T06:18:46', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3bb38afd-e61b-409e-976e-063067392d6a'	System	09 Mar 2021 11:57:27
User entered 'No (N)'	System	09 Mar 2021 11:57:27

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-03-09T06:18:52', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '3bb38afd-e61b-409e-976e-063067392d6a' User entered '09 Mar 2021 06:18:52'	System	09 Mar 2021 11:57:27
	System	09 Mar 2021 11:57:27

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-03-16T08:27:18', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '0df614f5-761e-4b33-a297-bd25eafa4d1f'	System	16 Mar 2021 12:27:32
User entered 'No (N)'	System	16 Mar 2021 12:27:32

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-03-16T08:27:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '0df614f5-761e-4b33-a297-bd25eafa4d1f'	System	16 Mar 2021 12:27:32
User entered 'No (N)'	System	16 Mar 2021 12:27:32

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-03-16T08:27:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '0df614f5-761e-4b33-a297-bd25eafa4d1f' User entered '16 Mar 2021 08:27:28'	System	16 Mar 2021 12:27:32
	System	16 Mar 2021 12:27:32

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-03-23T13:48:41', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a7353513-1348-4462-8f4c-ce8553f80f7d'	System	23 Mar 2021 17:48:55
User entered 'No (N)'	System	23 Mar 2021 17:48:55

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-03-23T13:48:45', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a7353513-1348-4462-8f4c-ce8553f80f7d'	System	23 Mar 2021 17:48:55
User entered 'No (N)'	System	23 Mar 2021 17:48:55

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-03-23T13:48:51', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'a7353513-1348-4462-8f4c-ce8553f80f7d'	System	23 Mar 2021 17:48:55
User entered '23 Mar 2021 13:48:51'	System	23 Mar 2021 17:48:55

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-03-31T12:33:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '0024ac82-c3c7-4119-be46-b20b95ceba45'	System	31 Mar 2021 16:33:32
User entered 'No (N)'	System	31 Mar 2021 16:33:32

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-03-31T12:33:25', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '0024ac82-c3c7-4119-be46-b20b95ceba45'	System	31 Mar 2021 16:33:32
User entered 'No (N)'	System	31 Mar 2021 16:33:32

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-03-31T12:33:30', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '0024ac82-c3c7-4119-be46-b20b95ceba45'	System	31 Mar 2021 16:33:32
User entered '31 Mar 2021 12:33:30'	System	31 Mar 2021 16:33:32

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-04-06T11:52:58', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c9898c9e-cc7f-454a-8bde-6ece705b1e21'	System	06 Apr 2021 15:53:13
User entered 'No (N)'	System	06 Apr 2021 15:53:13

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-04-06T11:53:06', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c9898c9e-cc7f-454a-8bde-6ece705b1e21'	System	06 Apr 2021 15:53:13
User entered 'No (N)'	System	06 Apr 2021 15:53:13

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-04-06T11:53:12', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'c9898c9e-cc7f-454a-8bde-6ece705b1e21'	System	06 Apr 2021 15:53:13
User entered '06 Apr 2021 11:53:12'	System	06 Apr 2021 15:53:13

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-04-14T14:44:13', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd28bf7b0-c9b3-493a-ab72-ee269b720735'	System	14 Apr 2021 18:44:23
User entered 'No (N)'	System	14 Apr 2021 18:44:23

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-04-14T14:44:17', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd28bf7b0-c9b3-493a-ab72-ee269b720735'	System	14 Apr 2021 18:44:23
User entered 'No (N)'	System	14 Apr 2021 18:44:23

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-04-14T14:44:21', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'd28bf7b0-c9b3-493a-ab72-ee269b720735'	System	14 Apr 2021 18:44:23
User entered '14 Apr 2021 14:44:21'	System	14 Apr 2021 18:44:23

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-04-20T06:20:15', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '1b77ca51-3f12-48bc-8ff3-65d0a566c91b'	System	20 Apr 2021 10:20:30
User entered 'No (N)'	System	20 Apr 2021 10:20:30

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-04-20T06:20:22', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '1b77ca51-3f12-48bc-8ff3-65d0a566c91b'	System	20 Apr 2021 10:20:30
User entered 'No (N)'	System	20 Apr 2021 10:20:30

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-04-20T06:20:29', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: '1b77ca51-3f12-48bc-8ff3-65d0a566c91b'	System	20 Apr 2021 10:20:30
User entered '20 Apr 2021 06:20:29'	System	20 Apr 2021 10:20:30

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[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 (5a3cd1c2722be1f8)', Time: '2021-04-28T10:00:19', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e41717e6-6b1f-412e-bed8-6477854b8503'	System	29 Apr 2021 01:15:59
User entered 'No (N)'	System	29 Apr 2021 01:15:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

Have you been exposed to someone with 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 (5a3cd1c2722be1f8)', Time: '2021-04-28T10:00:23', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e41717e6-6b1f-412e-bed8-6477854b8503'	System	29 Apr 2021 01:15:59
User entered 'No (N)'	System	29 Apr 2021 01:15:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a3cd1c2722be1f8)', Time: '2021-04-28T10:00:28', User OID: 'PatientReportedOutcome (US3722034)', ODM File OID: 'e41717e6-6b1f-412e-bed8-6477854b8503'	System	29 Apr 2021 01:15:59
User entered '28 Apr 2021 10:00:28'	System	29 Apr 2021 01:15:59

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 11:32:35

US3722034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:32:35
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 11:32:35

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:44
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	30 Oct 2020 14:43:33

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:44
User entered '25 Oct 2020'	Taylor Wilson (b) (4)	30 Oct 2020 14:43:33

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:44
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	30 Oct 2020 14:43:33

US3722034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:44
User entered empty.	Taylor Wilson (b) (4)	30 Oct 2020 14:43:33

US3722034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:44
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	30 Oct 2020 14:43:38

US3722034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:01:14
User entered 'I'	System	30 Oct 2020 14:43:38

US3722034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Sara Poff (b) (4)	30 Nov 2020 13:29:38

US3722034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '26 Nov 2020'	Sara Poff (b) (4)	30 Nov 2020 13:29:38

US3722034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Contact Made (CONTACT MADE)'	Sara Poff (b) (4)	30 Nov 2020 13:29:38

US3722034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	Sara Poff (b) (4)	30 Nov 2020 13:29:38

US3722034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:15
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Sara Poff (b) (4)	30 Nov 2020 13:29:42

US3722034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:15
User entered 'I'	System	30 Nov 2020 13:29:42

US3722034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Sara Poff (b) (4)	27 Dec 2020 03:53:35

US3722034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '26 Dec 2020'	Sara Poff (b) (4)	27 Dec 2020 03:53:35

US3722034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Contact Made (CONTACT MADE)'	Sara Poff (b) (4)	27 Dec 2020 03:53:35

US3722034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	Sara Poff (b) (4)	27 Dec 2020 03:53:35

US3722034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:21
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Sara Poff (b) (4)	27 Dec 2020 03:53:41

US3722034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:21
User entered 'I'	System	27 Dec 2020 03:53:41

US3722034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	26 Jan 2021 15:45:15

US3722034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '26 Jan 2021'	Taylor Wilson (b) (4)	26 Jan 2021 15:45:15

US3722034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	26 Jan 2021 15:45:15

US3722034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	Taylor Wilson (b) (4)	26 Jan 2021 15:45:15

US3722034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	26 Jan 2021 15:45:21

US3722034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:36
User entered 'I'	System	26 Jan 2021 15:45:21

US3722034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	09 Mar 2021 18:44:10
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered '9 Mar 2021'	Marlee Smith (b) (4)	09 Mar 2021 18:44:10
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	09 Mar 2021 18:44:10
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User entered 'VISIT4'	System	09 Mar 2021 18:44:10

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered '9 Mar 2021'	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered '13:05'	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User entered '9 Mar 2021 13:05'	System	29 Mar 2021 17:06:37

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered '97.7' F	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered '77'	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User entered 'bpm'	System	29 Mar 2021 17:06:37

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered '18'	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User entered 'breaths/min'	System	29 Mar 2021 17:06:37

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered '141'	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User entered 'mmHg'	System	29 Mar 2021 17:06:37

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered '84'	Marlee Smith (b) (4)	29 Mar 2021 17:06:37
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User entered 'mmHg'	System	29 Mar 2021 17:06:37

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44

US3722034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44

US3722034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	09 Mar 2021 18:44:15
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:48:00
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	09 Mar 2021 18:44:15
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	09 Mar 2021 18:44:22
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '9 Mar 2021'	Marlee Smith (b) (4)	09 Mar 2021 18:44:22
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '13:12'	Marlee Smith (b) (4)	09 Mar 2021 18:44:22
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User entered '9 Mar 2021 13:12'	System	09 Mar 2021 18:44:22

US3722034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	09 Mar 2021 18:44:25
	(b) (4)	

US3722034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:44
User entered '1'	System	09 Mar 2021 18:44:25

US3722034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	26 Mar 2021 17:06:22

US3722034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '26 Mar 2021'	Taylor Wilson (b) (4)	26 Mar 2021 17:06:22

US3722034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	26 Mar 2021 17:06:22

US3722034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	Taylor Wilson (b) (4)	26 Mar 2021 17:06:22

US3722034

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	26 Mar 2021 17:06:27

US3722034

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:11
User entered 'I'	System	26 Mar 2021 17:06:27

US3722034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	26 Apr 2021 16:56:35
	(b) (4)	

US3722034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '26 Apr 2021'	Taylor Wilson (b) (4)	26 Apr 2021 16:56:35
	(b) (4)	

US3722034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	26 Apr 2021 16:56:35
	(b) (4)	

US3722034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered empty.	Taylor Wilson (b) (4)	26 Apr 2021 16:56:35
	(b) (4)	

US3722034

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	26 Apr 2021 16:56:39
	(b) (4)	

US3722034

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 16:56:39

US3722034

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	26 Jan 2021 16:05:19

US3722034

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '9 Jan 2021'	Marlee Smith (b) (4)	26 Jan 2021 16:05:19

US3722034

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	26 Jan 2021 16:05:19

US3722034

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

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 16:05:19

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '09 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Marlee Smith (b) (4)	18 Feb 2021 20:39:03
User entered '26 Jan 2021'	(b) (4)	
	Marlee Smith (b) (4)	26 Jan 2021 16:05:53
	(b) (4)	

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:09:50

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:05:53

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per Sponsor Review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 11:47:56
' (Site from DM). Query 'Per Sponsor Review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.	Sara Poff (b) (4) (b) (4)	08 Apr 2021 14:16:24
' answered with 'Data entry error' (Site from DM). User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	08 Apr 2021 14:14:44
User opened query 'Per Sponsor Review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
' (Site from DM). User entered 'AMENDMENT 5 (AMENDMENT 5)' System WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:09:50

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:56:55
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Subject stated he had just complete chemo, sent an ePIP' (Site from System).	Marlee Smith (b) (4) (b) (4)	17 Feb 2021 14:06:39
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	17 Feb 2021 14:04:03
User entered '09 Jan 2021' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	17 Feb 2021 14:04:03
User entered '26 Jan 2021'	Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:05:53

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Placebo (Placebo)'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:05:53

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Placebo (Placebo)'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:05:53

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Placebo (Placebo)'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:05:53

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:05:53

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered '1'	System	26 Jan 2021 16:05:53

US3722034

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

Form: Unblinding

Generated On: 10 Jun 2021 09:31:41

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'I'	System	26 Jan 2021 16:05:53

US3722034

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered empty.	System	26 Jan 2021 16:44:35
DataPoint set to visible.	System	26 Jan 2021 16:05:53

US3722034

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered empty.	System	26 Jan 2021 16:44:35
DataPoint set to visible.	System	26 Jan 2021 16:05:53

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User accepted default value 'Pre-Dose (PREDOSE)'	Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	18 Feb 2021 20:39:03
Amendment Manager: User opened query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	16 Feb 2021 20:29:40
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Feb 2021 00:21:02
User entered '09 Jan 2021' reason for change: Data Entry Error	Sara Poff (b) (4)	03 Feb 2021 00:21:02
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	26 Jan 2021 16:44:35
User entered '26 Jan 2021'	System	26 Jan 2021 16:44:35
	Marlee Smith (b) (4)	
	(b) (4)	

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '10:35'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered '09 Jan 2021 10:35'	System	03 Feb 2021 00:21:02
User entered '26 Jan 2021 10:35'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '97.8' F	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Oral (Oral)'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '67'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'bpm'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '20'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'breaths/min'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '147'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'mmHg'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '81'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'mmHg'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:31:41

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered empty.	System	26 Jan 2021 16:44:35
DataPoint set to visible.	System	26 Jan 2021 16:05:53

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User accepted default value 'Post-Dose (POSTDOSE)'	Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	18 Feb 2021 20:39:03
Amendment Manager: User opened query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	16 Feb 2021 20:29:40
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Feb 2021 00:21:23
User entered '09 Jan 2021' reason for change: Data Entry Error	Sara Poff (b) (4)	03 Feb 2021 00:21:23
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	26 Jan 2021 16:44:35
User entered '26 Jan 2021'	System	26 Jan 2021 16:44:35
	Marlee Smith (b) (4)	
	(b) (4)	

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '11:11'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered '09 Jan 2021 11:11'	System	03 Feb 2021 00:21:23
User entered '26 Jan 2021 11:11'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '97.8' F	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Oral (Oral)'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '63'	Marlee Smith (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'bpm'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '20'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'breaths/min'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '139'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'mmHg'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '81'	(b) (4) Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:44:35

US3722034

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'mmHg'	System	26 Jan 2021 16:44:35

US3722034

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	26 Jan 2021 16:07:00

US3722034

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	
Amendment Manager: User opened query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	18 Feb 2021 20:39:03
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Feb 2021 20:29:40
User entered '09 Jan 2021' reason for change: Data Entry Error	System	03 Feb 2021 00:20:08
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Sara Poff (b) (4)	03 Feb 2021 00:20:08
User entered '26 Jan 2021'	(b) (4)	
	System	26 Jan 2021 16:07:00
	Marlee Smith (b) (4)	26 Jan 2021 16:07:00
	(b) (4)	

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:07:15

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:07:15

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

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)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	Marlee Smith (b) (4)	26 Jan 2021 16:07:15

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'mRNA-1273'	System	26 Jan 2021 16:07:15
DataPoint set to visible.	System	26 Jan 2021 16:05:53

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:17:16
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'Subject completed 3 days of chemo before visit OI-0. ePIP was sent and it was confirmed subject could get vaccine' (Site from System).	Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:08:53
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	26 Jan 2021 16:07:15
User entered '26 Jan 2021'	Marlee Smith (b) (4) (b) (4)	26 Jan 2021 16:07:15

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '10:41'	Marlee Smith (b) (4)	26 Jan 2021 16:07:15

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered '26 Jan 2021 10:41'	System	26 Jan 2021 16:07:15

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Left Arm (LEFT ARM)'	Marlee Smith (b) (4)	26 Jan 2021 16:07:15

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'ONCE'	System	26 Jan 2021 16:07:15

US3722034

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

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 16:07:15

US3722034

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	26 Jan 2021 16:06:05

US3722034

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	18 Feb 2021 20:39:03
Amendment Manager: User opened query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	16 Feb 2021 20:29:40
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Jan 2021 16:06:12
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	26 Jan 2021 16:06:12
User entered '9 Jan 2021' reason for change: Data Entry Error	Marlee Smith (b) (4)	26 Jan 2021 16:06:12
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	26 Jan 2021 16:06:05
User entered '26 Jan 2021'	System	26 Jan 2021 16:06:05
	Marlee Smith (b) (4)	26 Jan 2021 16:06:05
	(b) (4)	

US3722034

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '11:00'	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:06:05

US3722034

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered '9 Jan 2021 11:00'	System	26 Jan 2021 16:06:12
User entered '26 Jan 2021 11:00'	System	26 Jan 2021 16:06:05

US3722034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:00
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:06:22

US3722034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:41

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:00
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	(b) (4)	18 Feb 2021 20:39:03
Amendment Manager: User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	16 Feb 2021 20:29:40
User entered '9 Jan 2021'	Marlee Smith (b) (4)	26 Jan 2021 16:06:22
	(b) (4)	

US3722034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:00
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '11:03'	Marlee Smith (b) (4)	26 Jan 2021 16:06:22

US3722034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:31:41

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:00
User entered '9 Jan 2021 11:03'	System	26 Jan 2021 16:06:22

US3722034

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

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	26 Jan 2021 16:06:30

US3722034

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

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:01
User entered '1'	System	26 Jan 2021 16:06:30

US3722034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:34:42
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	03 Feb 2021 17:16:43

US3722034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:34:42
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '3 Feb 2021'	Marlee Smith (b) (4)	03 Feb 2021 17:16:43

US3722034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:34:42
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	03 Feb 2021 17:16:43

US3722034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:34:42
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	Marlee Smith (b) (4)	03 Feb 2021 17:16:43

US3722034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:34:42
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	03 Feb 2021 17:16:47

US3722034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:34:42
User entered 'I'	System	03 Feb 2021 17:16:47

US3722034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:34:42
User entered '1'	System	03 Feb 2021 17:16:47
DataPoint set to visible.	System	03 Feb 2021 17:16:47

US3722034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	25 Feb 2021 19:19:05

US3722034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '25 Feb 2021'	Marlee Smith (b) (4)	25 Feb 2021 19:19:05

US3722034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	25 Feb 2021 19:19:05

US3722034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'OLD29'	System	25 Feb 2021 19:19:05

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User accepted default value 'Pre-Dose (PREDOSE)'	Marlee Smith (b) (4) (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '25 Feb 2021'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '13:19'	Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered '25 Feb 2021 13:19'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '98' F	Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '83'	Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'bpm'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '16'	Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'breaths/min'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '131'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'mmHg'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '82'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'mmHg'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User accepted default value 'Post-Dose (POSTDOSE)'	Marlee Smith (b) (4) (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '25 Feb 2021'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '15:58'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered '25 Feb 2021 15:58'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '98.4' F	Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Oral (Oral)'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '75'	Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'bpm'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '18'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'breaths/min'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '132'	Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'mmHg'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '81'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:31:41

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'mmHg'	System	25 Feb 2021 19:19:54

US3722034

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:59

US3722034

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '25 Feb 2021'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:19:59

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:20:14

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:20:14

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

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)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	Marlee Smith (b) (4)	25 Feb 2021 19:20:14

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'mRNA-1273'	System	25 Feb 2021 19:20:14
DataPoint set to visible.	System	03 Feb 2021 17:16:47

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '25 Feb 2021'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:20:14

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '13:28'	(b) (4) Marlee Smith (b) (4)	25 Feb 2021 19:20:14

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered '25 Feb 2021 13:28'	System	25 Feb 2021 19:20:14

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Left Arm (LEFT ARM)'	Marlee Smith (b) (4)	25 Feb 2021 19:20:14

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'ONCE'	System	25 Feb 2021 19:20:14

US3722034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:31:41

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 19:20:14

US3722034

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Marlee Smith (b) (4)	25 Feb 2021 19:18:56

US3722034

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:10:46
User entered 'I'	System	25 Feb 2021 19:18:56

US3722034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	04 Mar 2021 14:52:18

US3722034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered '04 Mar 2021'	Taylor Wilson (b) (4)	04 Mar 2021 14:52:18

US3722034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	04 Mar 2021 14:52:18

US3722034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered empty.	Taylor Wilson (b) (4)	04 Mar 2021 14:52:18

US3722034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:05
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	04 Mar 2021 14:52:24

US3722034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:05
User entered 'I'	System	04 Mar 2021 14:52:24

US3722034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Apr 2021 15:56:16
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '5 Apr 2021'	Marlee Smith (b) (4)	05 Apr 2021 15:56:16
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	05 Apr 2021 15:56:16
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	05 Apr 2021 15:56:16

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '5 Apr 2021'	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '08:40'	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 08:40'	System	05 Apr 2021 15:56:39

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '96.8' F	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '70'	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 15:56:39

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '16'	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 15:56:39

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '135'	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 15:56:39

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '85'	Marlee Smith (b) (4)	05 Apr 2021 15:56:39
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 15:56:39

US3722034

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	05 Apr 2021 15:56:43
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	05 Apr 2021 15:56:43
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	05 Apr 2021 15:56:51
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '5 Apr 2021'	Marlee Smith (b) (4)	05 Apr 2021 15:56:51
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User entered '08:45'	Marlee Smith (b) (4)	05 Apr 2021 15:56:51
	(b) (4)	

US3722034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:31:41

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 08:45'	System	05 Apr 2021 15:56:51

US3722034

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:31:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: per previous query response 'due to entry error, worsening of back pain should not have been entered as an AE. will inactivate line', please agree to inactivate 'Worsening of back pain' on row 2.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:44:48
Query 'Per CDM: per previous query response 'due to entry error, worsening of back pain should not have been entered as an AE. will inactivate line', please agree to inactivate 'Worsening of back pain' on row 2.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	26 Apr 2021 15:03:24
User opened query 'Per CDM: per previous query response 'due to entry error, worsening of back pain should not have been entered as an AE. will inactivate line', please agree to inactivate 'Worsening of back pain' on row 2.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 14:01:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:06
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:14:25

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:14:45
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:14:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:40:30
User entered	System	06 Oct 2020 13:40:22
'USA-US083-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	06 Oct 2020 13:40:22

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer metastatic, LLT: Prostate cancer metastatic - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 18:44:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 18:44:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 00:15:19
Data point term sent to Coder	System	10 Nov 2020 22:22:24
DataPoint Un-verified.	Amy Ford (b) (4)	10 Nov 2020 22:21:40
	(b) (4)	
Coding entries removed.	Amy Ford (b) (4)	10 Nov 2020 22:21:40
	(b) (4)	
User entered 'Metastatic Castrate Sensitive Prostrate Cancer with Metastases' reason for change: New Information	Amy Ford (b) (4)	10 Nov 2020 22:21:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 05:39:35
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 05:39:35
Data point term sent to Coder	System	05 Oct 2020 18:18:43
User entered 'WORSENING OF PROSTATE CANCER'	Amy Ford (b) (4)	05 Oct 2020 18:18:36
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:37:42
User closed query 'IQVIA Medical query: Please clarify the start date of the event reported as 23Sep2020 considering that the source document reports concomitant medication Meloxicam started on 09Sep2020 to treat back pain related to metastatic prostate cancer and previous report of onset on 01Sep2020.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:11:03
Query 'IQVIA Medical query: Please clarify the start date of the event reported as 23Sep2020 considering that the source document reports concomitant medication Meloxicam started on 09Sep2020 to treat back pain related to metastatic prostate cancer and previous report of onset on 01Sep2020.' answered with 'updated' (Site from Safety).	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 14:47:08
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 14:46:55
User entered '01 Sep 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 14:46:55
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:42:28
User closed query 'Please verify start date. PDF file in CRIO indicates start date of 23Sep20.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:42:26
User opened query 'IQVIA Medical query: Please clarify the start date of the event reported as 23Sep2020 considering that the source document reports concomitant medication Meloxicam started on 09Sep2020 to treat back pain related to metastatic prostate cancer and previous report of onset on 01Sep2020.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:41:42
Query 'Please verify start date. PDF file in CRIO indicates start date of 23Sep20.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:57:08
User entered '23 Sep 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:56:48
User opened query 'Please verify start date. PDF file in CRIO indicates start date of 23Sep20.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 16:20:46

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sara Poff (b) (4)	13 Jan 2021 02:07:17
	(b) (4)	
User entered '01 Sep 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	13 Jan 2021 02:07:17
	(b) (4)	
User closed query 'Please verify start date, as source "record 4" indicates start date of 21Sep20, however, source AE log indicates start date of 23Sep20. Please ensure all records are correct and match. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:13:53
Query 'Please verify start date, as source "record 4" indicates start date of 21Sep20, however, source AE log indicates start date of 23Sep20. Please ensure all records are correct and match. Thank you.' answered with 'This has been clarified and the correct date of 23SEP2020 has been added. EDC is correct.' (Site from CRA).	Sara Poff (b) (4)	10 Nov 2020 18:50:04
	(b) (4)	
User opened query 'Please verify start date, as source "record 4" indicates start date of 21Sep20, however, source AE log indicates start date of 23Sep20. Please ensure all records are correct and match. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:13:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:12:30
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 16:12:28
Query 'Please verify start date, as source indicates 221Sep20. Thank you.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:12:25
User opened query 'Please verify start date, as source indicates 221Sep20. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:08:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '23 Sep 2020'	Amy Ford (b) (4)	05 Oct 2020 18:18:36
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 12:48:10
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 14:47:15
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Apr 2021 14:46:55
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:42:33
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	10 Feb 2021 15:57:36
User entered empty; reason for change Data Entry Error	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:57:36
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	10 Feb 2021 15:56:48
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Jan 2021 02:07:54
DataPoint Un-verified.	Sara Poff (b) (4) (b) (4)	13 Jan 2021 02:07:54
User entered '08:00' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	13 Jan 2021 02:07:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Jan 2021 02:07:17
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 15:57:36
User entered '23 Sep 2020 08:00'	System	10 Feb 2021 15:56:48
User entered '01 Sep 2020 08:00'	System	13 Jan 2021 02:07:54
User entered empty.	System	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:37:56
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	07 Apr 2021 15:51:22
DataPoint Un-verified.	Kayla Peay (b) (4)	07 Apr 2021 15:51:22
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	07 Apr 2021 15:51:22
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	07 Apr 2021 15:50:57
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:46:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	10 Mar 2021 20:57:04
	(b) (4)	
DataPoint Un-verified.	Kayla Peay (b) (4)	10 Mar 2021 20:56:45
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	10 Mar 2021 20:56:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Yes (Y)'	Amy Ford (b) (4)	05 Oct 2020 18:18:36
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:09:37
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:09:33
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'UPdated' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 15:51:55
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 15:50:57
User entered '24 Feb 2021' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 15:50:57
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:42:52
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	10 Mar 2021 20:57:04
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	10 Mar 2021 20:56:45

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 17:36:31
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'There is not a end date for this AE. Subject is still going through chemo and radiation ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	05 Mar 2021 19:11:25
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 16:02:37
User closed 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. Please keep query open until end date achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:55:45
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. Please keep query open until end date achieved.' answered with 'This will be on going for a very long time. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 22:38:30
User opened 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. Please keep query open until end date achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:59:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

1881 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	11 Nov 2020 21:09:12
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 'THIS EVENT HAS NOT ENDED, THEREFORE IS STILL ONGOING' (Site from Safety).	Taylor Wilson (b) (4)	10 Nov 2020 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
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)	22 Oct 2020 17:11:02
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)	22 Oct 2020 16:53:34
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 'This is still a ongoing event. ' (Site from Safety).	Sara Poff (b) (4)	21 Oct 2020 21:18:52
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)	14 Oct 2020 15:53:20
User entered empty.	Amy Ford (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 06:09:04
Query 'Data is required. Please provide.' answered with 'unknown time ' (Site from System).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 15:52:06
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Apr 2021 15:51:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'I'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
Query 'Per CDM: Please review Action taken with investigational product field. Per CCGs, Not Applicable is ONLY expected if Adverse event is prior to first dose/investigational product' canceled (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:04:33
User opened query 'Per CDM: Please review Action taken with investigational product field. Per CCGs, Not Applicable is ONLY expected if Adverse event is prior to first dose/investigational product' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:40:26
User entered 'Not Applicable (NOT APPLICABLE)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered 'I'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'PV query - please provide results of Abdominal CT done on 19 Oct 2020 (indicated in EDC). Please provide date of Cervical Spine CT scan mentioned in narrative and add this to Con procedures in EDC.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:09:27
Query 'PV query - please provide results of Abdominal CT done on 19 Oct 2020 (indicated in EDC). Please provide date of Cervical Spine CT scan mentioned in narrative and add this to Con procedures in EDC.' answered with 'Updated narrative.' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:16:59
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:46:56
User opened query 'PV query - please provide results of Abdominal CT done on 19 Oct 2020 (indicated in EDC). Please provide date of Cervical Spine CT scan mentioned in narrative and add this to Con procedures in EDC.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:42:07
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 14:39:10
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4)	05 Mar 2021 14:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered '0'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:09:46
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	16 Apr 2021 11:39:35
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please leave query open until information is obtained.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:09:41
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please leave query open until information is obtained.' answered with 'Updated outcome' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 15:52:19
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 15:50:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 15:50:57
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please leave query open until information is obtained.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 17:33:23

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 17:33:23
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Per PI, site will update status once records are received to show end of treatment cycles. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	15 Mar 2021 20:03:16
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:42:31
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:23:03
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Per PI, we will change outcome once last cycle of treatment is complete. ' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 20:57:33

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:31:36
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)	25 Nov 2020 12:55:49
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 'Subject will be handling this for a very long time ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 22:40:16
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)	20 Nov 2020 22:00:07
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)	11 Nov 2020 21:09:18
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 'RESOLUTION IS NOT EXPECTED IN NEAR FUTURE AS SUBJECT IS STILL CONTINUING TREATMENT FOR CANCER ' (Site from Safety).	Taylor Wilson (b) (4) (b) (4)	10 Nov 2020 21:26:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
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 17:11:24
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)	22 Oct 2020 16:53:36
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 'Still a ongoing issue. Will update when resolved. ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	21 Oct 2020 21:19:23
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)	14 Oct 2020 15:53:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:09:58
User closed query 'If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 17:09:57
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	16 Apr 2021 13:06:51
DataPoint Un-verified.	Kayla Peay (b) (4)	16 Apr 2021 13:06:51
	(b) (4)	
User entered 'Increased pain, osseous metastases, multiple bony lytic lesions, T9 and T12 for pain management' reason for change: Data Entry Error	Kayla Peay (b) (4)	16 Apr 2021 13:06:51
Query 'If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'Updated' (Site from CRA).	Kayla Peay (b) (4)	16 Apr 2021 11:42:38
	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	16 Apr 2021 11:39:35
User opened query 'If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 18:40:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:05:08
User entered empty.	Amy Ford (b) (4)	05 Oct 2020 18:18:36
	(b) (4)	

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:00
User closed query 'Per DM CLR: Narrative = POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:09:11
User closed query 'Per DM CLR: Narrative = SUBJECT REPORTED WORSENING OF BACK PAIN 09SEP2020. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:09:09
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:16:16

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD MEDICAL HISTORY OF PROSTATE CANCER DIAGNOSED IN 2017. SUBJECT REPORTED WORSENING OF BACK PAIN 09SEP2020. SUBJECT PRESENTED TODAY FOR DAY 57 AND REPORTED WORSENING OF PROSTATE CANCER. MEDICAL RECORD RELEASE OBTAINED AND SITE WILL UPDATE ONCE RECORDS ARE RECIVED AND REVIEWED. COLONOSCOPY SHOWED METAPLASTIC POLYPS XRAY OF ABDOMEN SHOWED MULTILEVEL LUMBAR SPONDYLOSIS CERVICAL XRAY SHOWED POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES. IMAGING FROM 11-4-2020: CT CHEST - SHOWS MULTIPLE LYTIC LESIONS WITHIN THE BONES; CT OF ABDOMEN AND PELVIS: RETROPERITONEAL AND BILATERAL PELVIC ADENOPATHY CONCERNING FOR METASTATIC LESIONS. MANY DEMONSTRATE HETEROGENEOUS AREAS OF DECREASED ATTENUATION SUGGESTING NECROSIS; NUCLEAR MEDICINE BONE SCAN - NO SCINTIGRAPHIC EVIDENCE OF OSSEOUS METASTASES. IMAGING FROM 9-18-2020: CT CHEST: MULTIPLE LYTIC LESIONS PRESENT WITHIN THE BONES CONCERNING FOR MULTIPLE MYELOMA OR METASTASIS, NO SIGNIFICANT PLEURAL OR PARENCHYMAL ABNORMALITY. CT CERVICAL SPINE: LYTIC CERVICAL SPINE LESIONS CONCERNING FOR MULTIPLE MYELOMA OR METASTASIS FROM UNKNOWN PRIMARY NEOPLASM. THE LESIONS ARE NOT SCLEROTIC AS TYPICALLY SEEN IN METASTATIC PROSTATE CANCER, SUSPECTED AGE-INDETERMINATE COMPRESSION FRACTURE AT C4. Abdominal CT on 19 OCT 2020 reported no significant abnormalities.' reason for change: Data Entry Error	Kayla Peay (b) (4)	07 Apr 2021 16:16:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

1909 of 2817

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = SUBJECT REPORTED WORSENING OF BACK PAIN 09SEP2020. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Will add as AE' (Site from DM).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 15:53:18
Query 'Per DM CLR: Narrative = POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Will add as AE' (Site from DM).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 15:53:10
User opened query 'Per DM CLR: Narrative = POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 02:08:37
User opened query 'Per DM CLR: Narrative = SUBJECT REPORTED WORSENING OF BACK PAIN 09SEP2020. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 02:08:32
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:03
User closed query 'PV Query: Please provide results of imaging done since 03 Sep. Per concomitant procedures, additional imaging was performed on 19 Oct and 04 Nov.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:22:59
Query 'PV Query: Please provide results of imaging done since 03 Sep. Per concomitant procedures, additional imaging was performed on 19 Oct and 04 Nov.' answered with 'Updated.' (Site from Safety).	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 20:57:34
DataPoint Un-verified.	Kayla Peay (b) (4) (b) (4)	10 Mar 2021 20:56:45

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD MEDICAL HISTORY OF PROSTATE CANCER DIAGNOSED IN 2017. SUBJECT REPORTED WORSENING OF BACK PAIN 09SEP2020. SUBJECT PRESENTED TODAY FOR DAY 57 AND REPORTED WORSENING OF PROSTATE CANCER. MEDICAL RECORD RELEASE OBTAINED AND SITE WILL UPDATE ONCE RECORDS ARE RECIVED AND REVIEWED. COLONOSCOPY SHOWED METAPLASTIC POLYPS XRAY OF ABDOMEN SHOWED MULTILEVEL LUMBAR SPONDYLOSIS CERVICAL XRAY SHOWED POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES. Imaging from 11-4-2020: CT Chest - shows multiple lytic lesions within the bones; CT of Abdomen and Pelvis: Retroperitoneal and bilateral pelvic adenopathy concerning for metastatic lesions. Many demonstrate heterogeneous areas of decreased attenuation suggesting necrosis; Nuclear Medicine Bone Scan - No scintigraphic evidence of osseous metastases. Imaging from 9-18-2020: CT CHEST: Multiple lytic lesions present within the bones concerning for multiple myeloma or metastasis, no significant pleural or parenchymal abnormality. CT Cervical Spine: Lytic cervical spine lesions concerning for multiple myeloma or metastasis from unknown primary neoplasm. The lesions are not sclerotic as typically seen in metastatic prostate cancer, suspected age-indeterminate compression fracture at C4.' reason for change: Data Entry Error	Kayla Peay (b) (4)	10 Mar 2021 20:56:45
User opened query 'PV Query: Please provide results of imaging done since 03 Sep. Per concomitant procedures, additional imaging was performed on 19 Oct and 04 Nov.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:30:56
User closed query 'PV Query: Please consider updating event start date to confirmed metastases (reported as 01 Sep via colonoscopy) ' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:07:41

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating event start date to confirmed metastases (reported as 01 Sep via colonoscopy) ' answered with 'Updated ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	13 Jan 2021 02:08:11
User opened query 'PV Query: Please consider updating event start date to confirmed metastases (reported as 01 Sep via colonoscopy) ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 02:44:36
User closed query 'PV Query: Please confirm if subject is undergoing radiation, chemo, and/or has a planned surgery.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:55:52
Query 'PV Query: Please confirm if subject is undergoing radiation, chemo, and/or has a planned surgery.' answered with 'Subject is undergoing chemo ' (Site from Safety).	Sara Poff (b) (4) (b) (4)	24 Nov 2020 22:35:21
User opened query 'PV Query: Please confirm if subject is undergoing radiation, chemo, and/or has a planned surgery.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:00:51
User closed query 'PV Query: Please provide results of diagnostic tests (i.e. bone scan, pelvic CT, etc) performed in evaluation of prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:09:47
User closed query 'PV Query: Please provide PSA results prior to start of study medication and at the time subject presented with prostate cancer' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:09:40
User closed query 'PV Query: Please provide histology and TNM stage of prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:09:26
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:09:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:15:42

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide results of diagnostic tests (i.e. bone scan, pelvic CT, etc) performed in evaluation of prostate cancer.' answered with 'COMPLETED' (Site from Safety). DataPoint Un-verified.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:20:46
	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:20:37
User entered 'SUBJECT HAD MEDICAL HISTORY OF PROSTATE CANCER DIAGNOSED IN 2017. SUBJECT REPORTED WORSENING OF BACK PAIN 09SEP2020. SUBJECT PRESENTED TODAY FOR DAY 57 AND REPORTED WORSENING OF PROSTATE CANCER. MEDICAL RECORD RELEASE OBTAINED AND SITE WILL UPDATE ONCE RECORDS ARE RECIVED AND REVIEWED. COLONOSCOPY SHOWED METAPLASTIC POLYPS XRAY OF ABDOMEN SHOWED MULTILEVEL LUMBAR SPONDYLOSIS CERVICAL XRAY SHOWED POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES.' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:20:37
Query 'PV Query: Please provide PSA results prior to start of study medication and at the time subject presented with prostate cancer' answered with 'all available information has been entered' (Site from Safety).	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:17:42
Query 'PV Query: Please provide histology and TNM stage of prostate cancer.' answered with 'all available information has been entered' (Site from Safety).	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:17:31
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'all available information has been entered' (Site from Safety). DataPoint Verified.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:17:18
	(b) (4), (b) (6)	10 Nov 2020 16:05:08

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of diagnostic tests (i.e. bone scan, pelvic CT, etc) performed in evaluation of prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:54:44
User opened query 'PV Query: Please provide PSA results prior to start of study medication and at the time subject presented with prostate cancer' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:54:18
User opened query 'PV Query: Please provide histology and TNM stage of prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:54:01
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:53:46
User entered 'SUBJECT HAD MEDICAL HISTORY OF PROSTATE CANCER DIAGNOSED IN 2017. SUBJECT REPORTED WORSENING OF BACK PAIN 09SEP2020. SUBJECT PRESENTED TODAY FOR DAY 57 AND REPORTED WORSENING OF PROSTATE CANCER. MEDICAL RECORD RELEASE OBTAINED AND SITE WILL UPDATE ONCE RECORDS ARE RECIVED AND REVIEWED.'	Amy Ford (b) (4) (b) (4)	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 18:18:36

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User coded data point as SOC: Investigations, HLGT: Water, electrolyte and mineral investigations, HLT: Mineral and electrolyte analyses, PT: Blood iron decreased, LLT: Iron low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:03:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:03:56
Data point term sent to Coder	System	10 Nov 2020 22:02:50
User entered 'low iron'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '4 Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'I'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 22:02:37

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:19:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:19:41
Data point term sent to Coder	System	10 Nov 2020 22:03:56
User entered 'neck pain'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '1 Sep 2020'	Amy Ford (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:30:38
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:04:29
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 22:03:49
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User entered empty.	System	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '4 Sep 2020'	Amy Ford (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:30:41
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:04:13
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 22:03:49
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User entered empty.	System	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amy Ford (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:04:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:04:19
User entered 'No (N)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:04:19
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:03:49
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'l'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User entered '0'	System	10 Nov 2020 22:04:19

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28
User entered '0'	System	10 Nov 2020 22:03:49

US3722034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:28

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 20:08:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 20:08:32
Data point term sent to Coder	System	05 Jan 2021 20:07:40
Coding entries removed.	Marlee Smith (b) (4) (b) (4)	05 Jan 2021 20:06:53
User entered 'intermittent CONSTIPATION' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	05 Jan 2021 20:06:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:06:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:06:54
Data point term sent to Coder	System	10 Nov 2020 22:06:01
User entered 'constipation'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '01 Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:30:57
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:06:14
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 22:05:59
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:56:31
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'Due to the medications that the subject has to take this is still ongoing. ' (Site from DM).	Sara Poff (b) (4) (b) (4)	24 Feb 2021 18:45:54
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 17:26:38
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:11:21
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	05 Jan 2021 20:07:02

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	30 Nov 2020 01:50:10
	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:38:58
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	02 Dec 2020 14:23:12
User entered '0' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	02 Dec 2020 14:23:06
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 04:09:51
User entered '1'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4)	02 Dec 2020 14:23:06
User entered '0'	(b) (4) Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 22:05:59

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per DM CLR: Please review the dates of this AE as it was noted to be within the dates of the recorded MH condition of Insomnia. Please reconcile and update applicable details so there is no overlap or delete if this is a duplicate record. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:22:02
Query 'Per DM CLR: Please review the dates of this AE as it was noted to be within the dates of the recorded MH condition of Insomnia. Please reconcile and update applicable details so there is no overlap or delete if this is a duplicate record. Otherwise, clarify.' answered with 'In AE, Subject's case of insomnia worsened during this time frame. In medical history insomnia started before AE' (Site from DM).	Marlee Smith (b) (4) (b) (4)	17 Mar 2021 19:00:53
User opened query 'Per DM CLR: Please review the dates of this AE as it was noted to be within the dates of the recorded MH condition of Insomnia. Please reconcile and update applicable details so there is no overlap or delete if this is a duplicate record. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:08:23
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:34:34
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia exacerbated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:42:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:42:41
Data point term sent to Coder	System	10 Nov 2020 22:24:25
User entered 'WORSENING OF INSOMNIA'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per CRIO this is not an MAAE. Please confirm and reconcile EDC or note in CRIO.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:49:42
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
Query 'Per CRIO this is not an MAAE. Please confirm and reconcile EDC or note in CRIO.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:15
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:07
User opened query 'Per CRIO this is not an MAAE. Please confirm and reconcile EDC or note in CRIO.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:45:13
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 20:39:05
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:34:36
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:34:37
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:34:39
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'per CRIO start date is 00Sep20' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:30:19
User closed query 'Please verify start date of worsening of insomnia. Insomnia is noted in Medical History with an end date of 02Nov20, which is after the date noted here for worsening.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:49:54
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
Query 'Please verify start date of worsening of insomnia. Insomnia is noted in Medical History with an end date of 02Nov20, which is after the date noted here for worsening.' answered with 'This has been updated to the correct date ' (Site from CRA).	Sara Poff (b) (4) (b) (4)	24 Feb 2021 18:47:04
Query 'per CRIO start date is 00Sep20' answered with '00 in EDC is non conformant data' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:56:15
User entered '01 Sep 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:07
User opened query 'per CRIO start date is 00Sep20' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:44:38
User opened query 'Please verify start date of worsening of insomnia. Insomnia is noted in Medical History with an end date of 02Nov20, which is after the date noted here for worsening.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:05:15
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:24:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:24:43
User entered '1 Sep 2020' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:43
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:24:04
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:31:04
Query 'Data is required. Please provide.' answered with 'UNKNOWN' (Site from System).	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:51
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 22:24:43
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User entered empty.	System	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per CRIO this event ended 03Nov20. Please verify and reconcile EDC or note in CRIO.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:30:30
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
Query 'Per CRIO this event ended 03Nov20. Please verify and reconcile EDC or note in CRIO.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:29
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:07
User opened query 'Per CRIO this event ended 03Nov20. Please verify and reconcile EDC or note in CRIO.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:45:49
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 20:36:47
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:34:43
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '02 Nov 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	24 Feb 2021 18:46:46
DataPoint Un-verified.	(b) (4) Marlee Smith (b) (4)	10 Feb 2021 15:55:07
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4) Marlee Smith (b) (4)	10 Feb 2021 15:55:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:34:45
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:35:40
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:38
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Feb 2021 15:55:07
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:34:48
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User entered empty.	System	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per CRIO, AE of worsening insomnia is noted as mild or Grade1. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:04
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
Query 'Per CRIO, AE of worsening insomnia is noted as mild or Grade1. Please reconcile.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:43
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:07
User opened query 'Per CRIO, AE of worsening insomnia is noted as mild or Grade1. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:37:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:46:19
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:46:21
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:46:23
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:46:24
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:46:26
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:46:29
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:46:31
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:46:32
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:46:34
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:46:36
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:46:41
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:46:43
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:46:45
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'None (NONE)'	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:47:12
User entered 'l'	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:47:35
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:47:37
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per CRIO, event has resolved. Please verify and reconcile in EDC or CRIO.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:11
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
Query 'Per CRIO, event has resolved. Please verify and reconcile in EDC or CRIO.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 15:55:07
User opened query 'Per CRIO, event has resolved. Please verify and reconcile in EDC or CRIO.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:47:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:47:43
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:47:45
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User entered '0'	System	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33
User entered '0'	System	10 Feb 2021 15:55:07
User entered '1'	System	10 Nov 2020 22:24:04

US3722034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:33

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:30:17
User coded data point as SOC: Gastrointestinal disorders, HLG: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:57:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:57:10
Data point term sent to Coder	System	19 Nov 2020 13:13:06
User closed query 'For coding purposes, please enter the location for METAPLASTIC POLYPS in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	System	19 Nov 2020 13:12:18
Query 'For coding purposes, please enter the location for METAPLASTIC POLYPS in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' answered with 'completed and updated ' (Site from System).	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:12:18
Data point term sent to Coder	System	19 Nov 2020 13:12:05
User entered 'METAPLASTIC POLYPS in colon' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Nov 2020 13:11:09
User opened query 'For coding purposes, please enter the location for METAPLASTIC POLYPS in order that the term may be coded accurately and to the appropriate body site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:46:34
Data point term sent to Coder	System	11 Nov 2020 01:21:38
User entered 'Metaplastic polyps'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:30:19
User entered 'Yes (Y)'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:30:21
User entered 'No (N)'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:30:26
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:30:28
User entered '01 Sep 2020'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:31:17
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:36
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 01:21:27
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User entered empty.	System	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:01
User entered 'No (N)'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:03
User entered '1 Sep 2020'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:31:19
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:42
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 01:21:27
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User entered empty.	System	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:13
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:52:14
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:16
User entered '0'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:18
User entered '0'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:19
User entered empty.	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:21
User entered empty.	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:24
User entered empty.	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:26
User entered empty.	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:52:28
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:30
User entered '0'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:31
User entered '0'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:52:33
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:36
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:52:37
User entered 'None (NONE)'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:56:08
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:56:10
User entered '0'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:56:12
User entered 'I'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:56:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:56:15
User entered empty.	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Per DM CLR: RQ: Response noted, however, the procedure recorded is just COLONOSCOPY. Please consider adding the POLYP REMOVAL together with COLONOSCOPY (e.g., COLONOSCOPY with POLYP REMOVAL) or add a separate recording of it in the Con Proc eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:18:43
Query 'Per DM CLR: RQ: Response noted, however, the procedure recorded is just COLONOSCOPY. Please consider adding the POLYP REMOVAL together with COLONOSCOPY (e.g., COLONOSCOPY with POLYP REMOVAL) or add a separate recording of it in the Con Proc eCRF. Otherwise, clarify.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	21 Jan 2021 14:45:27
User opened query 'Per DM CLR: RQ: Response noted, however, the procedure recorded is just COLONOSCOPY. Please consider adding the POLYP REMOVAL together with COLONOSCOPY (e.g., COLONOSCOPY with POLYP REMOVAL) or add a separate recording of it in the Con Proc eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:30:33
User closed query 'Per DM CLR: RQ: However, POLYP REMOVAL is not yet recorded in the Concomitant Procedure eCRF. Record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:29:01
Query 'Per DM CLR: RQ: However, POLYP REMOVAL is not yet recorded in the Concomitant Procedure eCRF. Record the procedure as appropriate. Otherwise, clarify.' answered with 'colonoscopy is under log line 2 in procedures' (Site from DM).	Marlee Smith (b) (4) (b) (4)	05 Jan 2021 20:09:04
User opened query 'Per DM CLR: RQ: However, POLYP REMOVAL is not yet recorded in the Concomitant Procedure eCRF. Record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 12:01:35

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that the subject had Polyp Removal. However, there is no corresponding Concomitant Procedure record that match this information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:46:33
Query 'Per DM CLR: Narrative indicates that the subject had Polyp Removal. However, there is no corresponding Concomitant Procedure record that match this information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	02 Dec 2020 14:24:40
User opened query 'Per DM CLR: Narrative indicates that the subject had Polyp Removal. However, there is no corresponding Concomitant Procedure record that match this information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 04:10:45
User entered 'Polyps removed during colonoscopy'	Amy Ford (b) (4)	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User entered '0'	System	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41
User entered '1'	System	11 Nov 2020 01:21:27

US3722034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:41:41

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Per CDM: Response noted, Please confirm if this event is the worsening condition of the event 'DEGENERATIVE DISC DISEASE WORSE AT L4-L5' noted on MH eCRF. If yes update AE term accordingly, else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 21:01:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Lumbar disc degeneration - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:50:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:50:00
Data point term sent to Coder	System	24 Feb 2021 18:49:14
Query 'Per CDM: Response noted, Please confirm if this event is the worsening condition of the event 'DEGENERATIVE DISC DISEASE WORSE AT L4-L5' noted on MH eCRF. If yes update AE term accordingly, else clarify in query response.' answered with 'Updated to corrected term wanted by CDM. ' (Site from DM).	Sara Poff (b) (4) (b) (4)	24 Feb 2021 18:48:56
Coding entries removed.	Sara Poff (b) (4) (b) (4)	24 Feb 2021 18:48:25
User entered 'DEGENERATIVE DISC DISEASE WORSE AT L4-L5' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	24 Feb 2021 18:48:25
User opened query 'Per CDM: Response noted, Please confirm if this event is the worsening condition of the event 'DEGENERATIVE DISC DISEASE WORSE AT L4-L5' noted on MH eCRF. If yes update AE term accordingly, else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:31:24
Query 'Per CDM: Response noted Please confirm if this event is the worsening condition of the event 'DEGENERATIVE DISC DISEASE WORSE AT L4-L5' noted on MH eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:30:02

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Response noted Please confirm if this event is the worsening condition of the event 'DEGENERATIVE DISC DISEASE WORSE AT L4-L5' noted on MH eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:29:32
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of DEGENERATIVE DISC DISEASE WORSE AT L4-L5 noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:29:32
Query 'Per DM CLR: Please confirm if this AE is a worsening of DEGENERATIVE DISC DISEASE WORSE AT L4-L5 noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'It does qualify as a AE ' (Site from DM).	Sara Poff (b) (4) (b) (4)	13 Jan 2021 02:09:46
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of DEGENERATIVE DISC DISEASE WORSE AT L4-L5 noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 04:11:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Lumbar spondylosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:01:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:01:37
Data point term sent to Coder	System	11 Nov 2020 01:24:42
User entered 'Multilevel lumbar spondylosis'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '1 Sep 2020'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 01:31:26
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:44
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 01:24:35
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'None (NONE)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:51
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:48:00
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 14:49:15
DataPoint Un-verified.	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 14:49:10
User entered '0' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	01 Apr 2021 14:49:10
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 02:08:50
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '1'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '1' reason for change: Data Entry Error	Marlee Smith (b) (4)	05 Mar 2021 14:39:42
User entered '0'	(b) (4) Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'x-ray of the abdomen performed on 01Sep2020 revealed multilevel lumbar spondylosis'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 01:24:35

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:52:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:52:52
Data point term sent to Coder	System	15 Jan 2021 14:52:26
User entered 'Anxiety'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '25 Sep 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 20:39:49
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'still ongoing' (Site from DM).	Marlee Smith (b) (4) (b) (4)	02 Feb 2021 14:30:14
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 17:26:20
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Grade 1/Mild (Grade 1/Mild)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Applicable (NOT APPLICABLE)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'None (NONE)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'I'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:47:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Jan 2021 14:51:40

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Cervical vertebral fracture, LLT: Cervical vertebral fracture C4 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Apr 2021 19:59:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:59:02
Data point term sent to Coder	System	25 Apr 2021 19:55:50
Query 'For coding purposes, please split POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES into separate entries. Also, speciy Pleural Change.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:55:03
User opened query 'For coding purposes, please split POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES into separate entries. Also, speciy Pleural Change.' (Site from System).	Coder Import (b) (4) (b) (4)	25 Apr 2021 12:32:41
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:02:46
Data point term sent to Coder	System	07 Apr 2021 16:30:28
User entered 'POSSIBLE C4 FRACTURE OR LYTIC CHANGES AS WELL AS PLEURAL CHANGES'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 18:18:12
User entered '1 Oct 2020' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	07 Apr 2021 18:18:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 16:59:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 16:59:15
User entered 'un Oct 2020' (non-conformant).	Marlee Smith (b) (4) (b) (4)	07 Apr 2021 16:59:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 16:30:24
User entered '1 Oct 2020' (non-conformant).	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered 'Yes (Y)'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered '0'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered '0'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered '0'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered '0'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered '0'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered '0'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 16:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 16:32:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:32:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 16:30:24
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 16:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 16:32:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:32:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 16:30:24
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 16:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 16:32:52
User entered 'None (NONE)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:32:52
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 16:30:24
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered 'I'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered '0'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered '0'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered empty.	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:02:46
User entered 'CT of Chest done for staging of cancer and findings were reported in SAE narrative and AE added in response to query.'	Kayla Peay (b) (4) (b) (4)	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 16:30:24

US3722034

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 16:30:24

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per SAE medical records, subject was give IV 100mL Isovue 370 contrast for abdominal and pelvic CT. Please update Con-Meds in source and EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:31:16
Query 'Per SAE medical records, subject was give IV 100mL Isovue 370 contrast for abdominal and pelvic CT. Please update Con-Meds in source and EDC.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	09 Mar 2021 20:30:38
User opened query 'Per SAE medical records, subject was give IV 100mL Isovue 370 contrast for abdominal and pelvic CT. Please update Con-Meds in source and EDC.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:02:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:20:13
User closed query 'Per ETRTR: Please confirm medication dosed for SAE Worsening of Prostate Cancer if new dose or medication was provided, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:52:45
Query 'Per ETRTR: Please confirm medication dosed for SAE Worsening of Prostate Cancer if new dose or medication was provided, thanks.' answered with 'records requested and site will update once received' (Site from CRA).	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:34
User opened query 'Per ETRTR: Please confirm medication dosed for SAE Worsening of Prostate Cancer if new dose or medication was provided, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 17:03:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:00:43
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 20:18:58

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:49:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:49:13
Data point term sent to Coder	System	10 Aug 2020 02:02:43
User entered 'NAPROXEN'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'HIP PAIN'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '220'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mg (mg)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'as needed (PRN)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 15:20:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'PER PROTOCOL THIS IS TO BE RECORDED' (Site from System).	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 02:02:01
User entered 'UN Jul 2020'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 02:02:01

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:14
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: ANTI-ANDROGENS, PRODUCT: ENZALUTAMIDE, PRODUCTSYNONYM: XTANDI - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Aug 2020 19:45:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Aug 2020 19:45:11
	(b) (4)	
Data point term sent to Coder	System	12 Aug 2020 19:44:39
Coding entries removed.	Kayla Peay (b) (4)	12 Aug 2020 19:44:07
	(b) (4)	
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: ANTI-ANDROGENS, PRODUCT: ENZALUTAMIDE, PRODUCTSYNONYM: XTANDI - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 22:28:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Aug 2020 22:28:49
	(b) (4)	
Data point term sent to Coder	System	10 Aug 2020 19:28:11
User entered 'xtandi'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:15
User entered 'No (N)'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:18
User entered 'prostate cancer' reason for change:	Kayla Peay (b) (4)	12 Aug 2020 19:44:07
Data Entry Error	(b) (4)	
User entered 'medical history'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:01:55
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:58:23
User entered '160'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:01:41
User entered 'mg (mg)'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:01:57
User entered empty.	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:01:58
User entered 'once daily (QD)'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:00
User entered empty.	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:02
User entered 'Oral (ORAL)'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:03
User entered empty.	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 06:42:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 19:27:55
User entered 'un UNK 2018'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:10
User entered '0'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Please verify if Xtandi is ongoing. Per Medical Records received for SAE, subject was instructed to take Xtandi for 30 days. Should this initial entry of Xtandi in EDC be ended and a new entry added for the medication as noted in medical records?' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:30:55
Query 'Please verify if Xtandi is ongoing. Per Medical Records received for SAE, subject was instructed to take Xtandi for 30 days. Should this initial entry of Xtandi in EDC be ended and a new entry added for the medication as noted in medical records?' answered with 'updated end time' (Site from CRA).	Marlee Smith (b) (4)	10 Feb 2021 15:59:44
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4)	10 Feb 2021 15:59:20
	(b) (4)	
User opened query 'Please verify if Xtandi is ongoing. Per Medical Records received for SAE, subject was instructed to take Xtandi for 30 days. Should this initial entry of Xtandi in EDC be ended and a new entry added for the medication as noted in medical records?' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:09:25
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 18:07:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:12
User entered 'Yes (Y)'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:44
DataPoint Un-verified.	Marlee Smith (b) (4)	10 Feb 2021 15:59:20
	(b) (4)	
User entered 'un Oct 2019' reason for change: Data	Marlee Smith (b) (4)	10 Feb 2021 15:59:20
Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:13
User entered empty.	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:17
User entered 'No (N)'	Kayla Peay (b) (4)	10 Aug 2020 19:27:55
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User entered '1'	System	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User entered '1'	System	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:14
User entered '804 (804)'	System	10 Aug 2020 19:27:55

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:10:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:10:43
Data point term sent to Coder Coding entries removed.	System Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:54:31 10 Nov 2020 21:53:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:25:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:25:50
Data point term sent to Coder Coding entries removed.	System Taylor Wilson (b) (4) (b) (4)	10 Nov 2020 21:24:42 10 Nov 2020 21:24:34

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 15:11:30
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 15:11:30
Data point term sent to Coder	System	14 Oct 2020 15:10:31
User entered 'Hydrocodone/Acetaminophen'	Amy Ford (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:05
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:07
User entered 'Metastatic Castrate Sensitive Prostrate Cancer with Metastases' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:53:50
User entered 'WORSENING OF PROSTATE CANCER' reason for change: Data Entry Error	Taylor Wilson (b) (4) (b) (4)	10 Nov 2020 21:24:34
User entered 'back pain'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:09
User entered '7.5-325'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:10
User entered 'mg (mg)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:12
User entered empty.	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:16
User entered 'as needed (PRN)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:18
User entered empty.	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:19
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:21
User entered empty.	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:32:54
DataPoint Un-verified.	Sara Poff (b) (4) (b) (4)	11 Nov 2020 01:00:14
User entered '23 Sep 2020' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	11 Nov 2020 01:00:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:41:22
User entered '21 Sep 2020'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:27
User entered '0'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:29
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:30
User entered empty.	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:41:32
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:10:15

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 14:56:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:56:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:07
Data point term sent to Coder User entered 'Meloxicam'	System Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:53:29 10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Back Pain related to Metastatic Castrate Sensitive Prostrate Cancer with Metastases'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '15'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mg (mg)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'once daily (QD)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '9 Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:52:35

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 16:03:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 16:03:59
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 16:03:30
Coding entries removed.	Marlee Smith (b) (4)	16 Feb 2021 16:03:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 21:56:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 21:56:49
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 21:55:36
User entered 'Tramadol'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:37:00
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 17:50:26
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	13 Jan 2021 14:10:24
DataPoint Un-verified.	Marlee Smith (b) (4)	13 Jan 2021 14:10:18
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4)	13 Jan 2021 14:10:18
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 17:47:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 12:57:30
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'The pain is due to the other medical hx that causes pain. ' (Site from DM).	Sara Poff (b) (4)	07 Mar 2021 15:57:49
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:47:31
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:59:17
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	16 Feb 2021 16:03:23
DataPoint Un-verified.	Marlee Smith (b) (4)	16 Feb 2021 16:03:16
User entered 'generalized PAIN' reason for change: Data Entry Error	Marlee Smith (b) (4)	16 Feb 2021 16:03:16
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:39:06

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 17:51:18
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 17:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'pain'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '50'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mg (mg)'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'as needed (PRN)'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Jun 2020'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Oct 2020'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4)	10 Nov 2020 21:55:17
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User entered empty.	System	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User entered empty.	System	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:25
User entered empty.	System	10 Nov 2020 21:55:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:58:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:58:41
Data point term sent to Coder	System	10 Nov 2020 21:57:38
User entered 'Flomax'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed 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) (4), (b) (6)	22 Jan 2021 21:21:23
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. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	21 Jan 2021 14:41:19
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)	06 Jan 2021 17:43:37
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Benign prostatic hyperplasia'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0.4'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mg (mg)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'once daily (QD)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Sep 2020'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:56:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
	(b) (4)	
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 17:09:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 17:09:53
	(b) (4)	
Data point term sent to Coder	System	15 Jan 2021 17:06:52
Coding entries removed.	Marlee Smith (b) (4)	15 Jan 2021 17:06:21
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 14:59:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 14:59:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 21:58:43
User entered 'MAGNESIUM CITRATE'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note that there is no AE GENERALIZED PAIN 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 20:10:01
Query 'Per DM CLR: Please note that there is no AE GENERALIZED PAIN 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 'generalized pain does not meet AE criteria' (Site from DM).	Marlee Smith (b) (4)	24 Feb 2021 20:58:14
User opened query 'Per DM CLR: Please note that there is no AE GENERALIZED PAIN 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)	13 Feb 2021 16:40:10
User closed query 'Per DM CLR: This Conmed is given for the AE# 5 CONSTIPATION. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:13:17
Query 'Per DM CLR: This Conmed is given for the AE# 5 CONSTIPATION. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'The generalized pain is due to BA caused from prostate cancer' (Site from DM).	Sara Poff (b) (4)	03 Feb 2021 00:18:56

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 19:13:34
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4)	15 Jan 2021 17:06:32
DataPoint Un-verified.	(b) (4)	
User entered 'CONSTIPATION/generalized PAIN' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 17:06:21
User opened query 'Per DM CLR: This Conmed is given for the AE# 5 CONSTIPATION. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 17:46:50
DataPoint Verified.	(b) (4), (b) (6)	
User entered 'CONSTIPATION/PAIN'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '300'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'mL (mL)'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'once daily (QD)'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'Oral (ORAL)'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered empty.	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Sep 2020'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered '0'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'UN Sep 2020'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:43:09
User entered 'No (N)'	Amy Ford (b) (4)	10 Nov 2020 21:57:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User entered '1'	System	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User entered '1'	System	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:33
User entered '804 (804)'	System	10 Nov 2020 21:57:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
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)	15 Jan 2021 14:37:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:37:53
Data point term sent to Coder	System	15 Jan 2021 14:36:59
User entered 'lorazepam'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Anxiety'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '.5'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '25 Sep 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:54:20
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:06:21
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:06:12
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:34:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:47:08

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 14:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:55:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:55:52
Data point term sent to Coder	System	15 Jan 2021 14:37:59
User entered 'Lactated ringers infusion'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Worsening of prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '100'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'ml/hr'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'continuous'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'IV'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '02 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:53:30
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:06:33
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:06:27
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:35:22

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 14:47:15
User entered 'No (N)'	Marlee Smith (b) (4)	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User entered empty.	System	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User entered empty.	System	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:11
User entered empty.	System	15 Jan 2021 14:37:48

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:21:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:21:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:55:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:55:53
Data point term sent to Coder	System	15 Jan 2021 14:39:14
User entered 'sodium chloride flush'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '5-40'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'mL (mL)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'other (OTHER)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Every 8 hours'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '2 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:52:20
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:06:45
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:06:40
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:35:40

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 14:47:20
User entered 'No (N)'	Marlee Smith (b) (4)	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User entered empty.	System	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User entered empty.	System	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:20
User entered empty.	System	15 Jan 2021 14:38:46

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:21:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:21:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:55:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:55:54
Data point term sent to Coder	System	15 Jan 2021 14:40:16
User entered 'sodium chloride flush'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '5-40'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'mL (mL)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '2 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:48:03
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:08:31
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:08:26
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:36:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 14:47:25
User entered 'No (N)'	Marlee Smith (b) (4)	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User entered empty.	System	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User entered empty.	System	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:26
User entered empty.	System	15 Jan 2021 14:39:52

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:54:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:54:53
Data point term sent to Coder	System	15 Jan 2021 14:41:17
User entered 'hydromorphone (PF)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0.5'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '2 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:48:20
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:08:45
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:08:39
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:36:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 14:47:31
User entered 'No (N)'	Marlee Smith (b) (4)	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User entered empty.	System	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User entered empty.	System	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:31
User entered empty.	System	15 Jan 2021 14:40:38

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: FLUMAZENIL, PRODUCTSYNONYM: ROMAZICON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:42:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:42:52
Data point term sent to Coder	System	15 Jan 2021 14:42:17
User entered 'romazicon'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0.2'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '2 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 14:47:36
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User entered empty.	System	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User entered empty.	System	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:35
User entered empty.	System	15 Jan 2021 14:41:27

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PHENOTHIAZINE DERIVATIVES, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:28:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:28:53
Data point term sent to Coder	System	15 Jan 2021 14:42:19
User entered 'Phenergan'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '6.25'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '2 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:49:47
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:08:13
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:08:07
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:36:47

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 14:47:41
User entered 'No (N)'	Marlee Smith (b) (4)	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User entered empty.	System	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User entered empty.	System	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:49
User entered empty.	System	15 Jan 2021 14:42:05

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
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)	15 Jan 2021 14:52:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:52:53
Data point term sent to Coder	System	15 Jan 2021 14:43:20
User entered 'Benadryl'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '12.5'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '2 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:49:56
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:07:54
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:07:48
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:37:12

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 14:47:46
User entered 'No (N)'	Marlee Smith (b) (4)	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User entered empty.	System	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User entered empty.	System	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:15:56
User entered empty.	System	15 Jan 2021 14:42:41

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:07:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:07:52
Data point term sent to Coder	System	15 Jan 2021 14:43:20
User entered 'marcaine'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '5'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Intravenous (INTRAVENOUS)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '2 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:50:03
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:07:38
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:07:33
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:37:25

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 14:47:51
User entered 'No (N)'	Marlee Smith (b) (4)	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User entered empty.	System	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User entered empty.	System	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:08
User entered empty.	System	15 Jan 2021 14:43:17

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please review medication name as it does not correspond to the indication, dosag, dose unit and route recorded. Review and correct as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:10:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN PORCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 08:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 08:54:42
Data point term sent to Coder	System	08 Apr 2021 13:22:49
Query 'Per DM CLR: Please review medication name as it does not correspond to the indication, dosag, dose unit and route recorded. Review and correct as appropriate. Otherwise, provide comment.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	08 Apr 2021 13:22:06
User entered 'PORCINE (heparin)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	08 Apr 2021 13:21:50
User opened query 'Per DM CLR: Please review medication name as it does not correspond to the indication, dosag, dose unit and route recorded. Review and correct as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:18:21
Data point term sent to Coder	System	03 Mar 2021 04:40:18
User closed query 'For coding purposes, the reported name cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	System	03 Mar 2021 04:40:02

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'For coding purposes, the reported name cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' answered with 'Active ingredient added ' (Site from System).	Sara Poff (b) (4)	03 Mar 2021 04:40:02
Data point term sent to Coder	System	03 Mar 2021 04:39:17
User entered 'PORCINE (desiccated natural thyroid)' reason for change: Data Entry Error	Sara Poff (b) (4)	03 Mar 2021 04:38:25
User opened query 'For coding purposes, the reported name cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	15 Jan 2021 15:34:54
Data point term sent to Coder	System	15 Jan 2021 14:45:21
User entered 'porcine'	Marlee Smith (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '500'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'IU (IU)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Other (OTHER)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Intercatheter'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '2 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:50:14
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:07:25
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:07:19
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:37:42

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Marlee Smith (b) (4)	15 Jan 2021 14:47:56
User entered 'No (N)'	Marlee Smith (b) (4)	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User entered empty.	System	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User entered empty.	System	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:18
User entered empty.	System	15 Jan 2021 14:44:23

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:45:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:45:52
Data point term sent to Coder	System	15 Jan 2021 14:45:22
User entered 'norco'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '325'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'as needed (PRN)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '29 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '2 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:50:28
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:07:11
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	16 Feb 2021 16:07:02
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:37:59

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User entered empty.	System	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User entered empty.	System	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:16:29
User entered empty.	System	15 Jan 2021 14:45:09

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: PLATINUM COMPOUNDS, PRODUCT: CARBOPLATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:56:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:56:56
Data point term sent to Coder	System	07 Mar 2021 16:00:54
Coding entries removed.	Sara Poff (b) (4) (b) (4)	07 Mar 2021 16:00:01
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: PLATINUM COMPOUNDS, PRODUCT: CARBOPLATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:53:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:53:52
Data point term sent to Coder	System	15 Jan 2021 14:46:22
User entered 'carboplatin'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '300' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	07 Mar 2021 16:00:01
User entered 'unk'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Mar 2021 16:00:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Mar 2021 16:00:01
User entered 'mg (mg)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	07 Mar 2021 16:00:01
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 14:46:04
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Mar 2021 16:00:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Mar 2021 16:00:01
User entered 'every month (QM)' reason for change: Sara Poff	(b) (4)	07 Mar 2021 16:00:01
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 14:46:04
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Mar 2021 16:00:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Mar 2021 16:00:01
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	07 Mar 2021 16:00:01
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 14:46:04
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '3 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User entered '3 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:44
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 16:54:11
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'This has been corrected ' (Site from DM).	Sara Poff (b) (4) (b) (4)	03 Mar 2021 04:41:19
User entered 'No (N)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	03 Mar 2021 04:41:01
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:38:18

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User entered '1'	System	07 Mar 2021 16:00:01
User entered empty.	System	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User entered '1'	System	07 Mar 2021 16:00:01
User entered empty.	System	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:07
User entered '802 (802)'	System	07 Mar 2021 16:00:01
User entered empty.	System	15 Jan 2021 14:46:04

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS, ATC: PODOPHYLLOTOXIN DERIVATIVES, PRODUCT: ETOPOSIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:53:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:53:53
Data point term sent to Coder	System	15 Jan 2021 14:47:23
User entered 'etoposide'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered 'prostate cancer'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered 'unk'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 12:57:44
Query 'Data is required. Please complete.' answered with 'Not told by medical records, subject does not know. ' (Site from System).	Sara Poff (b) (4) (b) (4)	07 Mar 2021 16:01:35
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 14:46:50
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 12:57:46
Query 'Data is required. Please complete.' answered with 'Not told by medical records, subject does not know. ' (Site from System).	Sara Poff (b) (4) (b) (4)	07 Mar 2021 16:01:40
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 14:46:50
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 12:57:48
Query 'Data is required. Please complete.' answered with 'Not told by medical records, subject does not know. ' (Site from System).	Sara Poff (b) (4) (b) (4)	07 Mar 2021 16:01:46
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 14:46:50
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered empty.	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered '3 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered '0'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User entered '3 Nov 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:32
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 12:57:51
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 16:06:05
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	04 Mar 2021 16:05:55
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 16:38:30

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User entered empty.	System	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User entered empty.	System	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:17:14
User entered empty.	System	15 Jan 2021 14:46:50

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
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, PRODUCTSYNONYM: ISOVUE 370 - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 10:38:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 10:38:42
	(b) (4)	
Data point term sent to Coder	System	09 Mar 2021 20:33:28
User entered 'ISOVUL 370' reason for change: Data Entry Error	Marlee Smith (b) (4)	09 Mar 2021 20:33:05
	(b) (4)	
Data point term sent to Coder	System	09 Mar 2021 20:32:27
User entered 'isovul'	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered 'No (N)'	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered 'abdominal and pelvic CT'	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered '100'	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered 'mL (mL)'	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered empty.	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 20:33:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 20:33:05
User entered 'once (ONCE)' reason for change: Data Entry Error	Marlee Smith (b) (4)	09 Mar 2021 20:33:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 20:31:53
User entered empty.	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered empty.	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered 'Other (OTHER)'	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered 'IV'	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered empty.	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered 'I'	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 20:33:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 20:33:05
User entered 'No (N)' reason for change: Data Entry Error	Marlee Smith (b) (4)	09 Mar 2021 20:33:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 20:31:53
User entered empty.	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	09 Mar 2021 20:33:45
User entered 'un UNK 2020' reason for change:	Marlee Smith (b) (4)	09 Mar 2021 20:33:45
Data Entry Error	(b) (4)	
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	09 Mar 2021 20:33:05
User entered empty.	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:10:28
User entered 'No (N)'	Marlee Smith (b) (4)	09 Mar 2021 20:31:53
	(b) (4)	

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User entered empty.	System	09 Mar 2021 20:31:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User entered empty.	System	09 Mar 2021 20:31:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:06:02
User entered empty.	System	09 Mar 2021 20:31:53

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:46:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 19:46:36
Data point term sent to Coder	System	20 Apr 2021 14:56:46
User entered 'Decacron'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered 'post chemo fatigue'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered '10'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered 'mg (mg)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered 'once daily (QD)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered 'Oral (ORAL)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered '31 Mar 2021'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered '0'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered 'Yes (Y)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

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

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered empty.	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:23
User entered 'No (N)'	Marlee Smith (b) (4) (b) (4)	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 14:55:49

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:31:41

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:23
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:37:42
User entered 'Yes (Y)' reason for change: New Information	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:26:59
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 20:19:03

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:41

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered '1 Sep 2020'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:27:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:56:50
DataPoint Un-verified.	Marlee Smith (b) (4)	21 Jan 2021 14:45:56
	(b) (4)	
User entered 'COLONOSCOPY with polyps removal' reason for change: Data Entry Error	Marlee Smith (b) (4)	21 Jan 2021 14:45:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'COLONOSCOPY'	Amy Ford (b) (4)	11 Nov 2020 01:27:34
	(b) (4)	

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'Adverse Event (AE)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:27:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:31:41

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:27:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:31:41

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered '1 Sep 2020'	Amy Ford (b) (4)	11 Nov 2020 01:28:04

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:31:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'X-RAY OF THE ABDOMEN'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:28:04

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'Adverse Event (AE)'	Amy Ford (b) (4)	11 Nov 2020 01:28:04

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:31:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:33
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered empty.	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:28:04

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:31:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered '3 Sep 2020'	Amy Ford (b) (4)	11 Nov 2020 01:31:44

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:31:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'CERVICAL XRAY'	Amy Ford (b) (4)	11 Nov 2020 01:31:44

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered 'Adverse Event (AE)'	Amy Ford (b) (4) (b) (4)	11 Nov 2020 01:31:44

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:31:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:36
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:08
User entered empty.	Amy Ford (b) (4)	11 Nov 2020 01:31:44

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:31:41

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:43:30
User closed query 'Per Medical Records, subject had CT chest with contrast on 18Sep20. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:43:28
Query 'Per Medical Records, subject had CT chest with contrast on 18Sep20. Please review and reconcile.' answered with 'updated' (Site from CRA).	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 16:00:46
User entered '18 Sep 2020' reason for change: Data Entry Error	Marlee Smith (b) (4) (b) (4)	10 Feb 2021 16:00:40
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 19:15:15
User opened query 'Per Medical Records, subject had CT chest with contrast on 18Sep20. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 19:15:07
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:38:35
User entered '19 Oct 2020'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:48:52

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:31:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:38:35
User entered 'CT Chest with contrast'	Marlee Smith (b) (4)	15 Jan 2021 14:48:52

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
User closed query 'Per DM CLR: "For Conproc #5-7". Indication = Adverse Event. However the corresponding AE "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 12:49:21
Query 'Per DM CLR: "For Conproc #5-7". Indication = Adverse Event. However the corresponding AE "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	05 Mar 2021 14:38:15
User opened query 'Per DM CLR: "For Conproc #5-7". Indication = Adverse Event. However the corresponding AE "Other Action Taken" does not reflect "Concomitant Procedure". Please ensure action taken reflects "Concomitant Procedure". Review and update necessary ecrfs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 06:04:52
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:38:35
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4) (b) (4)	15 Jan 2021 14:48:52

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:31:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:40
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:38:35
User entered empty.	Marlee Smith (b) (4)	15 Jan 2021 14:48:52

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:31:41

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered '19 Oct 2020'	Marlee Smith (b) (4)	15 Jan 2021 14:49:13

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:31:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered 'CT of abdomen'	Marlee Smith (b) (4)	15 Jan 2021 14:49:13

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4)	15 Jan 2021 14:49:13

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:31:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:44
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered empty.	Marlee Smith (b) (4)	15 Jan 2021 14:49:13

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:31:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered '19 Oct 2020'	Marlee Smith (b) (4)	15 Jan 2021 14:49:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:31:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered 'nuclear medicine bone scan'	Marlee Smith (b) (4)	15 Jan 2021 14:49:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4)	15 Jan 2021 14:49:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:31:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:47
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered empty.	Marlee Smith (b) (4)	15 Jan 2021 14:49:34

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:31:41

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered '4 Nov 2020'	Marlee Smith (b) (4)	15 Jan 2021 14:49:53

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:31:41

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered 'CT abdomen and pelvis'	Marlee Smith (b) (4)	15 Jan 2021 14:49:53

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:31:41

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered 'Adverse Event (AE)'	Marlee Smith (b) (4)	15 Jan 2021 14:49:53

US3722034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:31:41

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:50
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:48:54
User entered empty.	Marlee Smith (b) (4)	15 Jan 2021 14:49:53

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered '06/Oct/2020 13:41'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:31:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:41:50
User entered '11/Nov/2020 21:11'	System	11 Nov 2020 21:11:03

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:31:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:41:50
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 16:07:49
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 21:11:03

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:41:47
User entered '13/Jan/2021 16:07'	System	13 Jan 2021 16:07:59

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:31:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:41:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:36:49
User entered 'I'	(b) (4), (b) (6)	13 Jan 2021 16:07:59

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:41:46
User entered '11/Feb/2021 10:15'	System	11 Feb 2021 15:15:30

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:31:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:41:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:36:49
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 15:15:30

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:41:44
User entered '08/Mar/2021 11:37'	System	08 Mar 2021 17:37:00

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:31:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:44:36
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:41:44
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 17:37:00

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:41:40
User entered '11/Mar/2021 06:24'	System	11 Mar 2021 14:24:32

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:31:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:44:36
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:41:40
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 14:24:32

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:12:40
User entered '02/Apr/2021 13:12'	System	02 Apr 2021 17:13:01

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:31:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:12:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:44:36
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 17:13:01

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:12:38
User entered '08/Apr/2021 13:10'	System	08 Apr 2021 17:10:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:31:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:12:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:44:36
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 17:10:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'USA-US083-2020-MRNA-1273-P301000001'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

Serious

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'No (N)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Yes (Y)'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Luis'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'De La Cruz'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '2 Roper Corners Cir'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'Greenville'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered 'SC'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:02:55
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 13:41:14
User entered '29615'	System	06 Oct 2020 13:40:22

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:10:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:02:55
User entered 'US'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	19 Apr 2021 13:44:50
User entered '8'	System	08 Apr 2021 17:10:21
User entered '7'	System	02 Apr 2021 17:13:01
User entered '6'	System	11 Mar 2021 14:24:32
User entered '5'	System	08 Mar 2021 17:37:00
User entered '4'	System	11 Feb 2021 15:15:30
User entered '3'	System	13 Jan 2021 16:07:59
User entered '2'	System	11 Nov 2020 21:11:03
User entered '1'	System	06 Oct 2020 13:41:21

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:12:35
User entered '19/Apr/2021 13:44'	System	19 Apr 2021 13:44:50

US3722034

Folder: SAE USA-US083-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:31:41

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.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:12:35
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 13:44:50