

US3222611 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

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US3222611

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

[Participant ID](#)

US3222611

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

US3222611

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 17:54:54

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Date of Informed Consent (*dd MMM yyyy*) 17 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 17:54:54

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 17:54:54

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 17:54:54

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Condition	DIABETES TYPE II
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 17:54:54

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:05 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:05
Height (<i>xxx.x</i>)	162.0 cm
Weight (<i>xxx.x</i>)	68.0 kg
BMI (<i>xxx.x</i>)	25.91068 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 17:54:54

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify MECHANIC

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 17:54:54

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 17 SEP 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 146265

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:05 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:05
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

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 (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:11 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:11
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 SEP 2020

What was the treatment time? (00:00-23:59) 10:36 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 10:36

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 17 SEP 2020

Collection time (*00:00-23:59*) 10:24 (24 HR)

Collection date and time (derived) 17 SEP 2020 10:24

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Collection date (<i>dd MMM yyyy</i>)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:26	17 SEP 2020 10:26
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes
No

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

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

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

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

PC Time Stamp _____

PC Open Date & Time 17 SEP 2020 10:56

PC Close Date & Time 17 SEP 2020 13:26

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.7 °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 18 SEP 2020 06:41
PC Open Date & Time 17 SEP 2020 14:21
PC Close Date & Time 18 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

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

PC Time Stamp	18 SEP 2020 13:26
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

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

PC Time Stamp	19 SEP 2020 18:14
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 12:08
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

PC Time Stamp 21 SEP 2020 12:01

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 SEP 2020 17:15
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

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

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

PC Time Stamp	23 SEP 2020 13:27
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

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

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

Please select one response below

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

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

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

PC Time Stamp

PC Open Date & Time

17 SEP 2020 10:56

PC Close Date & Time

17 SEP 2020 13:26

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

18 SEP 2020 06:42

PC Open Date & Time

17 SEP 2020 14:21

PC Close Date & Time

18 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

18 SEP 2020 13:26

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

19 SEP 2020 18:13

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

20 SEP 2020 12:08

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

21 SEP 2020 12:02

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

22 SEP 2020 17:15

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

23 SEP 2020 13:27

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

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

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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

No

Yes

PC Time stamp

PC Open Date & Time

17 SEP 2020 10:56

PC Close Date & Time

17 SEP 2020 13:26

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

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

No
Yes

PC Time stamp	18 SEP 2020 06:43
PC Open Date & Time	17 SEP 2020 14:21
PC Close Date & Time	18 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 2

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 13:25
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 3

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 18:13
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 4

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

No

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 12:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 5

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

No

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	21 SEP 2020 12:02
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 6

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 17:16
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 7

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 13:26
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3222611

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT2

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:00 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 09:00
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:43 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 10:43
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3222611

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy) _____

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

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 15 OCT 2020

What was the treatment time? (00:00-23:59) 10:12 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 10:12

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

US3222611

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 15 OCT 2020

Collection time (*00:00-23:59*) 09:30 (24 HR)

Collection date and time (derived) 15 OCT 2020 09:30

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Collection date (<i>dd MMM yyyy</i>)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	15 OCT 2020 09:35
Nasopharyngeal Swab 2	No		

US3222611

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °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 15 OCT 2020 10:34

PC Open Date & Time 15 OCT 2020 10:32

PC Close Date & Time 15 OCT 2020 13:02

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °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	15 OCT 2020 14:31
PC Open Date & Time	15 OCT 2020 13:57
PC Close Date & Time	16 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 OCT 2020 18:11
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 OCT 2020 22:41
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °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 18 OCT 2020 18:35

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 OCT 2020 12:47
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

PC Time Stamp 20 OCT 2020 14:44

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 OCT 2020 18:24
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

15 OCT 2020 10:35

PC Open Date & Time

15 OCT 2020 10:32

PC Close Date & Time

15 OCT 2020 13:02

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

15 OCT 2020 14:31

PC Open Date & Time

15 OCT 2020 13:57

PC Close Date & Time

16 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	16 OCT 2020 18:11
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	17 OCT 2020 22:42
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

18 OCT 2020 18:36

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

19 OCT 2020 12:47

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

20 OCT 2020 14:43

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 7

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	21 OCT 2020 18:24
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

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

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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

No

Yes

PC Time stamp	15 OCT 2020 10:36
PC Open Date & Time	15 OCT 2020 10:32
PC Close Date & Time	15 OCT 2020 13:02

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

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

No

Yes

PC Time stamp	15 OCT 2020 14:32
PC Open Date & Time	15 OCT 2020 13:57
PC Close Date & Time	16 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 2

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

No

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	16 OCT 2020 18:12
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 3

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	17 OCT 2020 22:42
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 4

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	18 OCT 2020 18:36
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 5

HEADACHE

None

- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

None

- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

None

- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

None

- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	19 OCT 2020 12:48
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 6

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

No

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	20 OCT 2020 14:43
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 7

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

No

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

	Yes <input type="checkbox"/>
PC Time stamp	21 OCT 2020 18:26
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3222611

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (*dd MMM yyyy*)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:54:55

Generated On: 09 Jun 2021 16:09:03

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 18 NOV 2020

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

Folder OID VISIT3

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 17:54:55

Generated On: 09 Jun 2021 16:09:03

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222611

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:54:55

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3222611

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:54:55

Generated On: 09 Jun 2021 16:09:03

Was the sample collected? Yes No

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

Collection time (*00:00-23:59*) 10:20 (24 HR)

Collection date and time (derived) 18 NOV 2020 10:20

US3222611

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:55

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 68

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 75

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 82
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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 DEC 2020 08:46:22
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 89

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

No

Yes

Have you been exposed to someone with known SARS-CoV-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 06:45:32

Patient Cloud Open Date & Time 12 DEC 2020 00:01

Patient Cloud Close Date & Time 16 DEC 2020 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	21 DEC 2020 08:28:25
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 103

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

No

Yes

Have you been exposed to someone with known SARS-CoV-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 26 DEC 2020 12:23:38

Patient Cloud Open Date & Time 26 DEC 2020 00:01

Patient Cloud Close Date & Time 30 DEC 2020 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	03 JAN 2021 21:05:03
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	12 JAN 2021 16:49:55
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 124

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

No

Yes

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

No

Yes

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

Date and time of submission 17 JAN 2021 10:53:51

Patient Cloud Open Date & Time 16 JAN 2021 00:01

Patient Cloud Close Date & Time 20 JAN 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 131

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

No

Yes

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 12:36:57

Patient Cloud Open Date & Time 23 JAN 2021 00:01

Patient Cloud Close Date & Time 27 JAN 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 11:22:47
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	10 FEB 2021 18:25:39
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	13 FEB 2021 21:37:56
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 19:28:57
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission

27 FEB 2021 09:12:23

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 12:52:54
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	13 MAR 2021 07:39:26
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	21 MAR 2021 12:56:21
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 07:15:17
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 APR 2021 17:04:13
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 18:00:45
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 215

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

No

Yes

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

No

Yes

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

Date and time of submission 17 APR 2021 23:27:27

Patient Cloud Open Date & Time 17 APR 2021 00:01

Patient Cloud Close Date & Time 21 APR 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 09:05:22
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 229

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

No

Yes

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

No

Yes

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

Date and time of submission

01 MAY 2021 12:32:23

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 236

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

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 243

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

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 250

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 257

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	29 MAY 2021 00:01
Patient Cloud Close Date & Time	02 JUN 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 264

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 271

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 278

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 285

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 299

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 306

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 313

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 320

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 327

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	07 AUG 2021 00:01
Patient Cloud Close Date & Time	11 AUG 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 334

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 341

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 348

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 355

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2021 00:01
Patient Cloud Close Date & Time	08 SEP 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 362

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

Patient Cloud Open Date & Time	02 OCT 2021 00:01
Patient Cloud Close Date & Time	06 OCT 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 390

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 404

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 411

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 418

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 425

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 432

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 439

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 446

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 453

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 460

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 467

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 481

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 488

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 495

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 502

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 509

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	19 FEB 2022 00:01
Patient Cloud Close Date & Time	23 FEB 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 530

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	26 FEB 2022 00:01
Patient Cloud Close Date & Time	02 MAR 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 544

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 551

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 565

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 APR 2022 00:01

[Patient Cloud Close Date & Time](#) 06 APR 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 09 APR 2022 00:01

[Patient Cloud Close Date & Time](#) 13 APR 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 586

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	30 APR 2022 00:01
Patient Cloud Close Date & Time	04 MAY 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 600

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 607

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 614

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2022 00:01
Patient Cloud Close Date & Time	25 MAY 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 621

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 08 JUN 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 635

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 642

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 649

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 656

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#) 06 JUL 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 663

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 670

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 677

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 684

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	30 JUL 2022 00:01
Patient Cloud Close Date & Time	03 AUG 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 691

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 698

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 17 AUG 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 705

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 24 AUG 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 712

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 719

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 726

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 733

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 740

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2022 00:01
Patient Cloud Close Date & Time	28 SEP 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 747

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 754

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 761

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 768

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 26 OCT 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 775

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 782

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission	
Patient Cloud Open Date & Time	05 NOV 2022 00:01
Patient Cloud Close Date & Time	09 NOV 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#) 16 NOV 2022 23:59

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

DAY 796

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

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

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3222611

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:09:03

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 09:12:51

US3222611

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:54:24

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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	VISIT4

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 15:08:16

Generated On: 09 Jun 2021 16:09:03

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222611

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*) _____

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

US3222611

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 13 APR 2021

Collection time (*00:00-23:59*) 09:40 (24 HR)

Collection date and time (derived) 13 APR 2021 09:40

US3222611

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) _____

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

Comments _____

If Contact Not Made, please provide Comments _____

US3222611

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3222611

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:09:03

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"/>

US3222611

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:09:03

Generate Next COVID-19 Assessment

Yes

No

US3222611

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 FEB 2021

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

Folder OID UNBLND_DECIDE

US3222611

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 17:29:44

Generated On: 09 Jun 2021 16:09:03

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

US3222611

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Height	_____
Weight	_____
BMI (xxx.x)	_____

US3222611

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

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)	14 FEB 2021
Time of assessment (00:00-23:59)	11:14 (24 HR)
Vital Signs Date and Time (derived)	14 FEB 2021 11:14
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3222611

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

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)	14 FEB 2021
Time of assessment (00:00-23:59)	12:01 (24 HR)
Vital Signs Date and Time (derived)	14 FEB 2021 12:01
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3222611

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 FEB 2021

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

US3222611

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

What was the treatment date? (dd MMM yyyy) 14 FEB 2021

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

Treatment Date and Time (derived) 14 FEB 2021 11:24

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

US3222611

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 14 FEB 2021

Collection time (*00:00-23:59*) 11:15 (24 HR)

Collection date and time (derived) 14 FEB 2021 11:15

US3222611

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 14 FEB 2021

Collection time (*00:00 - 23:59*) 11:18

Collection Date and Time (derived) 14 FEB 2021 11:18

US3222611

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes No

Date of Contact or Contact Attempt (dd MMM yyyy) 22 FEB 2021

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

Comments SPOKE WITH SUBJECT/ NO NEW MEDS/ NO NEW ILLNESSES/ NO COVID SYMPTOMS/ (b) (6)

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:54:54

Generated On: 09 Jun 2021 16:09:03

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

US3222611

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:29:44

Generated On: 09 Jun 2021 16:09:03

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 15 MAR 2021

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

Folder OID OLD29

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 17:29:44

Generated On: 09 Jun 2021 16:09:03

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:00 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 11:00
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 17:29:44

Generated On: 09 Jun 2021 16:09:03

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	12:40 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 12:40
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3222611

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:29:44

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3222611

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 17:29:44

Generated On: 09 Jun 2021 16:09:03

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

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

What was the treatment date? (dd MMM yyyy) 15 MAR 2021

What was the treatment time? (00:00-23:59) 12:09 (24 HR)

Treatment Date and Time (derived) 15 MAR 2021 12:09

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

US3222611

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:29:44

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:29:44

Generated On: 09 Jun 2021 16:09:03

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3222611

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:29:44

Generated On: 09 Jun 2021 16:09:03

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222611

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 APR 2021

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

Folder OID OLD57

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222611

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 15:08:15

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*) _____

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 13 APR 2021

Collection time (*00:00-23:59*) 09:40 (24 HR)

Collection date and time (derived) 13 APR 2021 09:40

US3222611

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

AEID USA-US104-2020-MRNA-1273-P30
1000015

Adverse event LEFT BASAL GANGLIA
HEMORRHAGE

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) 29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 10 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 True

Hospital Admission Date (dd MMM yyyy) 29 OCT 2020

Hospital Discharge Date (dd MMM yyyy) 10 NOV 2020

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:08:12

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Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

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

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

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

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

Narrative _____

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

ADMISSION

29/OCT/2020

DISCHARGE

10/NOV/2020

55 YO MALE DW P/W
NUMBNESS
THE PATIENT PRESENTED
WITH RIGHT ARM AND RIGHT
LEG NUMBNESS AND
WEAKNESS, RIGHT
HEMIPARESIS. 29/OCT/2020 @
ONSET 10:20 AM WHILE AT
WORK. DENIES WEAKNESS.
EMS REPORTED PATIENT VERY
ATAXIC, LEANING TO THE
RIGHT WHEN TRYING TO
AMBULATE, ALMOST FELL.
PATIENT DENIES HX OF HTN,
NO ANTICOAGULATION. NO
FAMILY HX OF STROKES OR
ANEURYSMS. BP 184/98 ON EMS
ARRIVAL.
SENSATION (ARMS/LEGS/FACE)
COMPLETE SENSORY LOSS
DIAGNOSTICS
1. CAT SCAN – CT STROKE
ALERT 10/29/2020 TIME 12:18
PM.
FINDINGS: LEFT BASAL
GANGLIA HEMORRHAGE
MEASURING 3.2 X 1.6 CM WITH
MILD SURROUNDING EDEMA.
2. COLOR AND SPECTRAL
DOPPLER EVAL OF

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

THE ARTERIAL VASCULATURE
IN BOTH LOWER EXTREMITIES.

FINDINGS: NO ARTERIAL
OCCLUSION. NO EVIDENCE OF
ELEVATED VELOCITIES TO
SUGGEST FOCAL STENOSIS.

3. A RIGHT LOWER EXTREMITY
SONOGRAM OF THE DEEP
VENOUS SYSTEM OF THE
LOWER EXTREMITY WAS
PERFORMED ASSESSING GRAY
SCALE APPEARANCE, COLOR,
DOPPLER FLOW,
AUGMENTATION AND
COMPRESSIBILITY.

FINDINGS: NO EVIDENCE OF
DVT IN THE RIGHT LOWER
EXTREMITY.

4. MRA HEAD WAS
PERFORMED. 2D TIME OF
FLIGHT TECHNIQUE WAS
UTILIZED. 3D REFORMATTED
IMAGES ALSO OBTAINED.
FINDINGS: NORMAL MRA OF
THE HEAD

5. MRI OF THE BRAIN. AXIAL,
SAGITTAL, AND CORONAL
IMAGES WERE OBTAINED
USING T1, T2, T2 FLAIR AND
DIFFUSION WEIGHTED
SEQUENCES.

FINDINGS: EXTENSIVE
PERIVENTRICULAR CHRONIC
MICROVASCULAR ISCHEMIC
CHANGES ARE NOTED. LEFT

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

BASAL GANGLIA
HEMORRHAGE WITH
SURROUNDING EDEMA
UNCHANGED WHEN
COMPARED TO THE PRIOR
STUDY.

29/OCT/2020

ECG NORMAL

VITALS

PULSE OX 98%

B/P 143/73

B/P MEAN 96

O2 DELIVERY ROOM AIR

PULSE 92

RESP 18

TEMP 36.9

MEDICATIONS

FAMOTIDINE 20 MG BID PO

NICARDIPINE HCL 50 MG

TITRATE IV

DEXTROSE 250 ML

NICARDIPINE HCL 50 MG X1FED

ONE IV

DEXTROSE 250 ML.

LABS (COAGULATION)

PT (9.0 - 11.6 SEC) 10.4

INR (2.0 - 3.0) 1.0 L

PTT (SP) (24.0 - 32.0 SEC) 27.1

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

AEID

Adverse event

HYPERTENSION

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes

No

Start date (dd MMM yyyy)

29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

10 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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 15:08:12

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	ALTHOUGH NOW TREATED WITH MEDICATION WILL CONTINUE WITH DIAGNOSIS
Narrative	THIS NEW DIAGNOSIS IS SECONDARY TO THE SAE.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

AEID

Adverse event

GAIT DYSFUNCTION AND
ADL'S AND SELF-CARE
DEFICITS

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)

29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

10 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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	NO BILATERAL FEET CONTROL, RIGHT SIDE OF BODY PARALYSIS.
Narrative	THIS DIAGNOSIS IS SECONDARY TO THE SAE
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

AEID	
Adverse event	DYSLIPIDEMIA
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)	29 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	THIS HAS BEEN TREATED WITH MEDICATION HOWEVER WILL NEVER RESOLVE WITHOUT MEDICATION.
Narrative	THIS DIAGNOSIS IS SECONDARY TO THE SAE.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

AEID

Adverse event

MILD EXPRESSIVE AND
RECEPTIVE APHASIA.

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)

29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

10 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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	RESIDUAL EFFECTS FROM CVA
Narrative	THIS DIAGNOSIS IS SECONDARY TO THE SAE.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

AEID	
Adverse event	NERVE PAIN SECONDARY TO STROKE
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)	12 JAN 2021
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 type="radio"/> Grade 3/Severe <input checked="" 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"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

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 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 Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

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

Yes

No

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

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication AMBIEN

Prophylaxis Yes
No

Indication INSOMNIA

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 15:08:12

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) _____ UN UNK 2019

Start date completely unknown _____ False

Ongoing? Yes No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication METFORMIN

Prophylaxis Yes
No

Indication DIABETES TYPE II

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2014

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication OMEPROZOLE

Prophylaxis Yes
No

Indication GERD

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2014

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication ROSUVASTATIN

Prophylaxis Yes
No

Indication HYPERCHOLESTEROLEMIA/
DYSLIPIDEMIA

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:08:12

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Name of Medication TRULICITY

Prophylaxis Yes
No

Indication DIABETESTYPE II

Dose per administration 1.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2014

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication XIGDUO

Prophylaxis Yes
No

Indication DIABETES TYPE II

Dose per administration 5/500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2014

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication NICARDIPINE

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (<i>dd MMM yyyy</i>)	29 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	29 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	_____
Interval Dosage Unit Number (derived)	_____
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication DEXTROSE

Prophylaxis Yes
No

Indication DIABETES TYPE II

Dose per administration 250

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (<i>dd MMM yyyy</i>)	29 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	30 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"/>

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication FAMOTIDINE

Prophylaxis Yes
No

Indication GERD

Dose per administration 20

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 29 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication TRAMADOL

Prophylaxis Yes
No

Indication NERVE PAIN SECONDARY TO STROKE

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

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	12 JAN 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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication GABAPENTIN

Prophylaxis Yes
No

Indication NERVE PAIN FROM STROKE HE
RECENTLY HAD

Dose per administration 300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	12 JAN 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"/>

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication BACLOFEN

Prophylaxis Yes
No

Indication NERVE PAIN FROM STROKE HE
RECENTLY HAD

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

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	12 JAN 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"/>

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Name of Medication AMITRIPTYLINE

Prophylaxis Yes
No

Indication NERVE PAIN FROM STROKE HE
RECENTLY HAD

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

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 12 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 15:08:12

Generated On: 09 Jun 2021 16:09:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 OCT 2020	CT SCAN OF THE BRAIN	Adverse Event	
29 OCT 2020	COLOR/SPECTRAL DOPPLER	Adverse Event	
29 OCT 2020	SONOGRAM - LOWER RIGHT EXTREMITIES	Adverse Event	
31 OCT 2020	MRI HEAD AND NECK	Adverse Event	
29 OCT 2020	ECG	Adverse Event	
31 OCT 2020	CHEMISTRY, PT, PTT, AND COMPLETE BLOOD COUNT	Adverse Event	
31 OCT 2020	MRA	Adverse Event	

US3222611

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:09:03

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Due to SARS-COV-2

Other

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

US3222611

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:09:03

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

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

SAEID	USA-US104-2020-MRNA-1273-P30 1000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

SAEID	USA-US104-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 18:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

SAEID	USA-US104-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/NOV/2020 18:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

SAEID	USA-US104-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:04
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

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

SAEID	USA-US104-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/NOV/2020 18:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 17:54:23

Generated On: 09 Jun 2021 16:09:03

SAEID	USA-US104-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	21/DEC/2020 10:59
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.	<input checked="" type="checkbox"/> True

Audit

US3222611 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222611

Form: Participant Creation

Generated On: 09 Jun 2021 16:09:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'US3222611'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:24:31

US3222611

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	17 Sep 2020 14:45:17

US3222611

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:24:32

US3222611

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	17 Sep 2020 14:45:17

US3222611

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'SCRN'	System	17 Sep 2020 14:45:17

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:24:34

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '55'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'YEARS'	System	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered '55'	System	17 Sep 2020 14:45:30

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Male (M)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '1'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:03

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:36:11

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 Sep 2020'	Jennifer Dittman (b) (4)	17 Sep 2020 14:45:30

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'Sep 2020'	System	17 Sep 2020 14:45:30

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered '2020'	System	17 Sep 2020 14:45:30

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Amendment 3 (3)'	Jennifer Dittman (b) (4)	17 Sep 2020 14:45:30

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	17 Sep 2020 14:45:30

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	17 Sep 2020 14:45:30
	(b) (4)	

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	17 Sep 2020 14:45:30
	(b) (4)	

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	17 Sep 2020 14:45:30

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:24:32

US3222611

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered '1'	System	17 Sep 2020 14:45:36

US3222611

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	17 Sep 2020 14:45:36

US3222611

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:09:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:39:27

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 18:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 18:40:47
Data point term sent to Coder	System	21 Sep 2020 18:40:15
User entered 'DIABETES TYPE II'	Albert Garcia (b) (4)	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'UN UNK 2014'	Albert Garcia (b) (4)	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Albert Garcia (b) (4)	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'Jan 2014'	System	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered '2014'	System	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered empty.	System	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered empty.	System	21 Sep 2020 18:40:12

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 18:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 18:41:50
Data point term sent to Coder	System	21 Sep 2020 18:41:19
User entered 'HYPERCHOLESTEROLEMIA'	Albert Garcia (b) (4)	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'UN UNK 2014' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:41:58
User entered 'UN UNK 2019'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'Jan 2014'	System	21 Sep 2020 18:41:58
User entered 'Jan 2019'	System	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered '2014'	System	21 Sep 2020 18:41:58
User entered '2019'	System	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered empty.	System	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered empty.	System	21 Sep 2020 18:40:42

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:50:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 16:50:51
Data point term sent to Coder	System	14 Nov 2020 16:50:26
Coding entries removed.	douglas winter (b) (4)	14 Nov 2020 16:49:51
User entered 'GERD' reason for change: Data Entry Error	(b) (4)	
User entered 'GERD' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 16:49:51
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 18:41:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 18:41:49
Data point term sent to Coder	System	21 Sep 2020 18:41:19
User entered 'ACID REFLUX'	Albert Garcia (b) (4)	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'UN UNK 2014'	Albert Garcia (b) (4)	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4)	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4)	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'Jan 2014'	System	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered '2014'	System	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered empty.	System	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered empty.	System	21 Sep 2020 18:41:01

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 18:42:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 18:42:45
Data point term sent to Coder	System	21 Sep 2020 18:42:20
User entered 'INSOMNIA'	Albert Garcia (b) (4)	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'UN UNK 2019'	Albert Garcia (b) (4)	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'Jan 2019'	System	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered '2019'	System	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered empty.	System	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered empty.	System	21 Sep 2020 18:41:33

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 Sep 2020'	(b) (4) Albert Garcia (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '10:05'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered '17 Sep 2020 10:05'	System	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '162.0' cm	(b) (4) Albert Garcia (b) (4)	21 Sep 2020 18:54:34
DataPoint set to visible.	(b) (4) System	17 Sep 2020 14:45:36

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '68.0' kg	(b) (4) Albert Garcia (b) (4)	21 Sep 2020 18:54:34
DataPoint set to visible.	(b) (4) System	17 Sep 2020 14:45:36

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered '25.91068'	System	21 Sep 2020 18:54:34
DataPoint set to visible.	System	17 Sep 2020 14:45:36

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'kg/m2'	System	21 Sep 2020 18:54:34
DataPoint set to visible.	System	17 Sep 2020 14:45:36

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	Albert Garcia (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	Albert Garcia (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'bpm'	System	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	Albert Garcia (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'breaths/min'	System	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	Albert Garcia (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'mmHg'	System	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	Albert Garcia (b) (4)	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User entered 'mmHg'	System	21 Sep 2020 18:54:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34

US3222611

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34

US3222611

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:54:45

US3222611

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:54:45

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'MECHANIC'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '1'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:34
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:55:25

US3222611

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	17 Sep 2020 14:45:56

US3222611

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 Sep 2020'	(b) (4) Jennifer Dittman (b) (4)	17 Sep 2020 14:45:56
	(b) (4)	

US3222611

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	17 Sep 2020 14:45:56

US3222611

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'VISIT1'	System	17 Sep 2020 14:45:56

US3222611

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:14:43

US3222611

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:03

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '146265'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:14:43

US3222611

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:03

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:14:43

US3222611

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:03

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:56:41

US3222611

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:03

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:56:41

US3222611

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:03

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:56:41

US3222611

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:56:41

US3222611

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:56:41

US3222611

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:03

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	21 Sep 2020 18:56:41
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 09:24:12
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:24:10

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '10:05'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '17 Sep 2020 10:05'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '37.1' C	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Oral (Oral)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '87'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'bpm'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '14'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'breaths/min'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '141'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'mmHg'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '88'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'mmHg'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered missing code ND - Not Done.	(b) (4) Albert Garcia (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '11:11'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '17 Sep 2020 11:11'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '37.1' C	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Oral (Oral)'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '82'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'bpm'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '14'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'breaths/min'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '143'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'mmHg'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '88'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'mmHg'	System	21 Sep 2020 18:59:34

US3222611

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:44

US3222611

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:59:44

US3222611

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	17 Sep 2020 14:46:53

US3222611

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	17 Sep 2020 14:46:53
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Jennifer Dittman (b) (4)	17 Sep 2020 14:46:53

US3222611

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 14:46:53

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '17 Sep 2020'	Jennifer Dittman (b) (4)	17 Sep 2020 14:46:53

US3222611

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '10:36'	(b) (4) Jennifer Dittman (b) (4)	17 Sep 2020 14:46:53
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '17 Sep 2020 10:36'	System	17 Sep 2020 14:46:53

US3222611

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	17 Sep 2020 14:46:53

US3222611

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'ONCE'	System	17 Sep 2020 14:46:53

US3222611

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 14:46:53

US3222611

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:26

US3222611

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17SEP2020 is recorded under Visit 1 Day1 in EDC, however the same is reported under Visit 1 Day 1 with date 12SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 04:25:18
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17SEP2020 is recorded under Visit 1 Day1 in EDC, however the same is reported under Visit 1 Day 1 with date 12SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate, else clarify.' answered with '17/SEP/2020 IS THE CORRECT DATE' (Site from DM).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:43:09
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17SEP2020 is recorded under Visit 1 Day1 in EDC, however the same is reported under Visit 1 Day 1 with date 12SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:39:07
User entered '17 Sep 2020'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:26

US3222611

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '10:24'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:26

US3222611

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '17 Sep 2020 10:24'	System	21 Sep 2020 19:02:26

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:09:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 17-SEP-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:11:29
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 17-SEP-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F60jui' (Site from DM).	gail lavine (b) (4) (b) (4)	20 Jan 2021 13:44:27
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 17-SEP-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:25:41
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 17SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 12SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 04:23:10

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:09:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 17SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 12SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with '17/SEP/2020 IS THE CORRECT DATE' (Site from DM).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:42:36
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 17SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 12SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:08:27
User entered '17 Sep 2020'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:44

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:44

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:44

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '10:26'	(b) (4) Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:44

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '17 Sep 2020 10:26'	System	21 Sep 2020 19:02:44

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:44

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:44

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 19:02:44

US3222611

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered empty.	System	21 Sep 2020 19:02:44

US3222611

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User closed query 'Per CDM: Visit 2 forms not completed. Please complete.' (Site from DM).	(b) (4)	26 Oct 2020 15:26:02
Query 'Per CDM: Visit 2 forms not completed. Please complete.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	16 Oct 2020 17:09:28
User opened query 'Per CDM: Visit 2 forms not completed. Please complete.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:52:49
User entered 'Yes (Y)'	Albert Garcia (b) (4)	21 Sep 2020 19:10:31

US3222611

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '1'	System	21 Sep 2020 19:10:31

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Sep 2020 10:56'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Sep 2020 13:26'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:41:07', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'de4503d4-4ee7-48c3-946a-cf69804aa261'	System	18 Sep 2020 10:41:40
User entered 'Yes (Y)'	System	18 Sep 2020 10:41:40

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:41:19', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'de4503d4-4ee7-48c3-946a-cf69804aa261'	System	18 Sep 2020 10:41:40
User entered '98.7'	System	18 Sep 2020 10:41:40

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:41:26', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'de4503d4-4ee7-48c3-946a-cf69804aa261'	System	18 Sep 2020 10:41:40
User entered 'No (N)'	System	18 Sep 2020 10:41:40

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:41:37', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'de4503d4-4ee7-48c3-946a-cf69804aa261'	System	18 Sep 2020 10:41:40
User entered '18 Sep 2020 06:41'	System	18 Sep 2020 10:41:40

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Sep 2020 14:21'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 2'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:26:15', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7ad6d95b-dce6-4b44-8ff7-ff43a50ca4d8'	System	18 Sep 2020 17:26:34
User entered 'Yes (Y)'	System	18 Sep 2020 17:26:34

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:26:25', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7ad6d95b-dce6-4b44-8ff7-ff43a50ca4d8'	System	18 Sep 2020 17:26:34
User entered '98.7'	System	18 Sep 2020 17:26:34

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:26:29', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7ad6d95b-dce6-4b44-8ff7-ff43a50ca4d8'	System	18 Sep 2020 17:26:34
User entered 'No (N)'	System	18 Sep 2020 17:26:34

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:26:33', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7ad6d95b-dce6-4b44-8ff7-ff43a50ca4d8'	System	18 Sep 2020 17:26:34
User entered '18 Sep 2020 13:26'	System	18 Sep 2020 17:26:34

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 3'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:14:18', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd8f990b2-ed00-43d6-9e07-582fb805d23b'	System	19 Sep 2020 22:14:43
User entered 'Yes (Y)'	System	19 Sep 2020 22:14:43

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:14:27', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd8f990b2-ed00-43d6-9e07-582fb805d23b'	System	19 Sep 2020 22:14:43
User entered '98.7'	System	19 Sep 2020 22:14:43

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:14:33', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd8f990b2-ed00-43d6-9e07-582fb805d23b'	System	19 Sep 2020 22:14:43
User entered 'No (N)'	System	19 Sep 2020 22:14:43

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:14:39', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd8f990b2-ed00-43d6-9e07-582fb805d23b'	System	19 Sep 2020 22:14:43
User entered '19 Sep 2020 18:14'	System	19 Sep 2020 22:14:43

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 4'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:08:18', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '4db6be8b-a01c-4710-9ffe-5e362d4ee865'	System	20 Sep 2020 16:08:44
User entered 'Yes (Y)'	System	20 Sep 2020 16:08:44

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:08:28', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '4db6be8b-a01c-4710-9ffe-5e362d4ee865'	System	20 Sep 2020 16:08:44
User entered '97.8'	System	20 Sep 2020 16:08:44

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:08:35', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '4db6be8b-a01c-4710-9ffe-5e362d4ee865'	System	20 Sep 2020 16:08:44
User entered 'No (N)'	System	20 Sep 2020 16:08:44

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:08:40', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '4db6be8b-a01c-4710-9ffe-5e362d4ee865'	System	20 Sep 2020 16:08:44
User entered '20 Sep 2020 12:08'	System	20 Sep 2020 16:08:44

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 5'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:01:45', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a932da75-12af-4adf-8f95-fb7c3f26cda0'	System	21 Sep 2020 16:13:11
User entered 'Yes (Y)'	System	21 Sep 2020 16:13:11

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:01:52', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a932da75-12af-4adf-8f95-fb7c3f26cda0' User entered '98.1'	System	21 Sep 2020 16:13:11
	System	21 Sep 2020 16:13:11

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:01:55', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a932da75-12af-4adf-8f95-fb7c3f26cda0'	System	21 Sep 2020 16:13:11
User entered 'No (N)'	System	21 Sep 2020 16:13:11

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:01:58', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a932da75-12af-4adf-8f95-fb7c3f26cda0'	System	21 Sep 2020 16:13:11
User entered '21 Sep 2020 12:01'	System	21 Sep 2020 16:13:11

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 6'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:18', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0b006fb7-0011-4375-91e1-43b8048fb9e1'	System	22 Sep 2020 21:15:37
User entered 'Yes (Y)'	System	22 Sep 2020 21:15:37

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:26', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0b006fb7-0011-4375-91e1-43b8048fb9e1'	System	22 Sep 2020 21:15:37
User entered '98.2'	System	22 Sep 2020 21:15:37

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:29', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0b006fb7-0011-4375-91e1-43b8048fb9e1'	System	22 Sep 2020 21:15:37
User entered 'No (N)'	System	22 Sep 2020 21:15:37

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:33', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0b006fb7-0011-4375-91e1-43b8048fb9e1'	System	22 Sep 2020 21:15:37
User entered '22 Sep 2020 17:15'	System	22 Sep 2020 21:15:37

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 7'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:27:17', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '884ae08f-81c3-41bd-9ee9-5ccedc5d8e34'	System	23 Sep 2020 17:27:34
User entered 'Yes (Y)'	System	23 Sep 2020 17:27:34

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:27:23', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '884ae08f-81c3-41bd-9ee9-5ccedc5d8e34'	System	23 Sep 2020 17:27:34
User entered '98.7'	System	23 Sep 2020 17:27:34

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:27:27', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '884ae08f-81c3-41bd-9ee9-5ccedc5d8e34'	System	23 Sep 2020 17:27:34
User entered 'No (N)'	System	23 Sep 2020 17:27:34

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:27:30', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '884ae08f-81c3-41bd-9ee9-5ccedc5d8e34'	System	23 Sep 2020 17:27:34
User entered '23 Sep 2020 13:27'	System	23 Sep 2020 17:27:34

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Sep 2020 10:56'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Sep 2020 13:26'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:41:49', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'cd680e13-6117-49a0-9f29-eea2c72fd404'	System	18 Sep 2020 10:42:22
User entered 'None (1)'	System	18 Sep 2020 10:42:22

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:41:54', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'cd680e13-6117-49a0-9f29-eea2c72fd404'	System	18 Sep 2020 10:42:22
User entered 'No (N)'	System	18 Sep 2020 10:42:22

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:41:58', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'cd680e13-6117-49a0-9f29-eea2c72fd404'	System	18 Sep 2020 10:42:22
User entered 'No (N)'	System	18 Sep 2020 10:42:22

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:42:12', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'cd680e13-6117-49a0-9f29-eea2c72fd404'	System	18 Sep 2020 10:42:22
User entered 'None (1)'	System	18 Sep 2020 10:42:22

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:42:20', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'cd680e13-6117-49a0-9f29-eea2c72fd404'	System	18 Sep 2020 10:42:22
User entered '18 Sep 2020 06:42'	System	18 Sep 2020 10:42:22

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Sep 2020 14:21'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 2'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:44', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f5093309-c80c-4448-ae3-20fc13cfe849'	System	18 Sep 2020 17:26:09
User entered 'None (1)'	System	18 Sep 2020 17:26:09

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:50', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f5093309-c80c-4448-ae3-20fc13cfe849'	System	18 Sep 2020 17:26:09
User entered 'No (N)'	System	18 Sep 2020 17:26:09

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:54', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f5093309-c80c-4448-ae3-20fc13cfe849'	System	18 Sep 2020 17:26:09
User entered 'No (N)'	System	18 Sep 2020 17:26:09

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:58', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f5093309-c80c-4448-ae3-20fc13cfe849'	System	18 Sep 2020 17:26:09
User entered 'None (1)'	System	18 Sep 2020 17:26:09

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:26:04', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f5093309-c80c-4448-ae3-20fc13cfe849'	System	18 Sep 2020 17:26:09
User entered '18 Sep 2020 13:26'	System	18 Sep 2020 17:26:09

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 3'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:13:34', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '77abad46-829a-41bb-bc6e-1c55fc9f60ff'	System	19 Sep 2020 22:13:57
User entered 'None (1)'	System	19 Sep 2020 22:13:57

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:13:40', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '77abad46-829a-41bb-bc6e-1c55fc9f60ff'	System	19 Sep 2020 22:13:57
User entered 'No (N)'	System	19 Sep 2020 22:13:57

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:13:43', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '77abad46-829a-41bb-bc6e-1c55fc9f60ff'	System	19 Sep 2020 22:13:57
User entered 'No (N)'	System	19 Sep 2020 22:13:57

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:13:48', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '77abad46-829a-41bb-bc6e-1c55fc9f60ff'	System	19 Sep 2020 22:13:57
User entered 'None (1)'	System	19 Sep 2020 22:13:57

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:13:55', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '77abad46-829a-41bb-bc6e-1c55fc9f60ff'	System	19 Sep 2020 22:13:57
User entered '19 Sep 2020 18:13'	System	19 Sep 2020 22:13:57

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 4'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:44', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ee2ed96e-40e0-40c7-8463-bb67d9da3860'	System	20 Sep 2020 16:08:08
User entered 'None (1)'	System	20 Sep 2020 16:08:08

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:48', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ee2ed96e-40e0-40c7-8463-bb67d9da3860'	System	20 Sep 2020 16:08:08
User entered 'No (N)'	System	20 Sep 2020 16:08:08

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:51', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ee2ed96e-40e0-40c7-8463-bb67d9da3860'	System	20 Sep 2020 16:08:08
User entered 'No (N)'	System	20 Sep 2020 16:08:08

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:08:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ee2ed96e-40e0-40c7-8463-bb67d9da3860'	System	20 Sep 2020 16:08:08
User entered 'None (1)'	System	20 Sep 2020 16:08:08

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:08:05', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ee2ed96e-40e0-40c7-8463-bb67d9da3860'	System	20 Sep 2020 16:08:08
User entered '20 Sep 2020 12:08'	System	20 Sep 2020 16:08:08

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 5'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:03', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'dd5c897c-f774-43dc-ae44-3df4d42677a5'	System	21 Sep 2020 16:14:01
User entered 'None (1)'	System	21 Sep 2020 16:14:01

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:06', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'dd5c897c-f774-43dc-ae44-3df4d42677a5'	System	21 Sep 2020 16:14:01
User entered 'No (N)'	System	21 Sep 2020 16:14:01

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:09', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'dd5c897c-f774-43dc-ae44-3df4d42677a5'	System	21 Sep 2020 16:14:01
User entered 'No (N)'	System	21 Sep 2020 16:14:01

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:11', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'dd5c897c-f774-43dc-ae44-3df4d42677a5'	System	21 Sep 2020 16:14:01
User entered 'None (1)'	System	21 Sep 2020 16:14:01

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:15', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'dd5c897c-f774-43dc-ae44-3df4d42677a5'	System	21 Sep 2020 16:14:01
User entered '21 Sep 2020 12:02'	System	21 Sep 2020 16:14:01

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 6'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:39', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9bed1580-f82c-4eec-b5fd-2accadfe31e9'	System	22 Sep 2020 21:15:54
User entered 'None (1)'	System	22 Sep 2020 21:15:54

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:42', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9bed1580-f82c-4eec-b5fd-2accadfe31e9'	System	22 Sep 2020 21:15:54
User entered 'No (N)'	System	22 Sep 2020 21:15:54

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:45', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9bed1580-f82c-4eec-b5fd-2accadfe31e9'	System	22 Sep 2020 21:15:54
User entered 'No (N)'	System	22 Sep 2020 21:15:54

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:48', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9bed1580-f82c-4eec-b5fd-2accadfe31e9'	System	22 Sep 2020 21:15:54
User entered 'None (1)'	System	22 Sep 2020 21:15:54

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:52', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9bed1580-f82c-4eec-b5fd-2accadfe31e9'	System	22 Sep 2020 21:15:54
User entered '22 Sep 2020 17:15'	System	22 Sep 2020 21:15:54

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 7'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:56', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea56b0e1-c363-4fb2-86b4-86eb0608f196'	System	23 Sep 2020 17:27:14
User entered 'None (1)'	System	23 Sep 2020 17:27:14

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:59', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea56b0e1-c363-4fb2-86b4-86eb0608f196'	System	23 Sep 2020 17:27:14
User entered 'No (N)'	System	23 Sep 2020 17:27:14

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:27:02', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea56b0e1-c363-4fb2-86b4-86eb0608f196'	System	23 Sep 2020 17:27:14
User entered 'No (N)'	System	23 Sep 2020 17:27:14

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:27:06', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea56b0e1-c363-4fb2-86b4-86eb0608f196'	System	23 Sep 2020 17:27:14
User entered 'None (1)'	System	23 Sep 2020 17:27:14

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:27:09', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea56b0e1-c363-4fb2-86b4-86eb0608f196'	System	23 Sep 2020 17:27:14
User entered '23 Sep 2020 13:27'	System	23 Sep 2020 17:27:14

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Sep 2020 10:56'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Sep 2020 13:26'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:42:30', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c895201-0fc1-44cc-a2ca-f31d227fc9eb'	System	18 Sep 2020 10:43:07
User entered 'None (0)'	System	18 Sep 2020 10:43:07

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:42:34', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c895201-0fc1-44cc-a2ca-f31d227fc9eb'	System	18 Sep 2020 10:43:07
User entered 'None (0)'	System	18 Sep 2020 10:43:07

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:42:39', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c895201-0fc1-44cc-a2ca-f31d227fc9eb'	System	18 Sep 2020 10:43:07
User entered 'None (0)'	System	18 Sep 2020 10:43:07

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:42:44', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c895201-0fc1-44cc-a2ca-f31d227fc9eb'	System	18 Sep 2020 10:43:07
User entered 'None (0)'	System	18 Sep 2020 10:43:07

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:42:49', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c895201-0fc1-44cc-a2ca-f31d227fc9eb'	System	18 Sep 2020 10:43:07
User entered 'None (0)'	System	18 Sep 2020 10:43:07

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:42:53', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c895201-0fc1-44cc-a2ca-f31d227fc9eb'	System	18 Sep 2020 10:43:07
User entered 'None (0)'	System	18 Sep 2020 10:43:07

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:43:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c895201-0fc1-44cc-a2ca-f31d227fc9eb'	System	18 Sep 2020 10:43:07
User entered 'No (N)'	System	18 Sep 2020 10:43:07

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T06:43:06', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c895201-0fc1-44cc-a2ca-f31d227fc9eb' User entered '18 Sep 2020 06:43'	System	18 Sep 2020 10:43:07
	System	18 Sep 2020 10:43:07

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Sep 2020 14:21'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 2'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:15', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd10d6d5f-3955-49a8-bc6f-707669082e02'	System	18 Sep 2020 17:25:43
User entered 'None (0)'	System	18 Sep 2020 17:25:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:18', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd10d6d5f-3955-49a8-bc6f-707669082e02'	System	18 Sep 2020 17:25:43
User entered 'None (0)'	System	18 Sep 2020 17:25:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:21', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd10d6d5f-3955-49a8-bc6f-707669082e02'	System	18 Sep 2020 17:25:43
User entered 'None (0)'	System	18 Sep 2020 17:25:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:25', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd10d6d5f-3955-49a8-bc6f-707669082e02'	System	18 Sep 2020 17:25:43
User entered 'None (0)'	System	18 Sep 2020 17:25:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:27', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd10d6d5f-3955-49a8-bc6f-707669082e02'	System	18 Sep 2020 17:25:43
User entered 'None (0)'	System	18 Sep 2020 17:25:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:30', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd10d6d5f-3955-49a8-bc6f-707669082e02'	System	18 Sep 2020 17:25:43
User entered 'None (0)'	System	18 Sep 2020 17:25:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:34', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd10d6d5f-3955-49a8-bc6f-707669082e02'	System	18 Sep 2020 17:25:43
User entered 'No (N)'	System	18 Sep 2020 17:25:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-18T13:25:38', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd10d6d5f-3955-49a8-bc6f-707669082e02'	System	18 Sep 2020 17:25:43
User entered '18 Sep 2020 13:25'	System	18 Sep 2020 17:25:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 3'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:12:41', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '824b78ac-b457-49fe-bd1a-41406e2b1c69'	System	19 Sep 2020 22:13:28
User entered 'None (0)'	System	19 Sep 2020 22:13:28

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:12:46', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '824b78ac-b457-49fe-bd1a-41406e2b1c69'	System	19 Sep 2020 22:13:28
User entered 'None (0)'	System	19 Sep 2020 22:13:28

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:12:50', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '824b78ac-b457-49fe-bd1a-41406e2b1c69'	System	19 Sep 2020 22:13:28
User entered 'None (0)'	System	19 Sep 2020 22:13:28

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:12:55', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '824b78ac-b457-49fe-bd1a-41406e2b1c69'	System	19 Sep 2020 22:13:28
User entered 'None (0)'	System	19 Sep 2020 22:13:28

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:13:05', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '824b78ac-b457-49fe-bd1a-41406e2b1c69'	System	19 Sep 2020 22:13:28
User entered 'None (0)'	System	19 Sep 2020 22:13:28

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:13:11', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '824b78ac-b457-49fe-bd1a-41406e2b1c69'	System	19 Sep 2020 22:13:28
User entered 'None (0)'	System	19 Sep 2020 22:13:28

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:13:19', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '824b78ac-b457-49fe-bd1a-41406e2b1c69'	System	19 Sep 2020 22:13:28
User entered 'No (N)'	System	19 Sep 2020 22:13:28

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-19T18:13:26', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '824b78ac-b457-49fe-bd1a-41406e2b1c69'	System	19 Sep 2020 22:13:28
User entered '19 Sep 2020 18:13'	System	19 Sep 2020 22:13:28

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 4'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:09', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9db3914b-407d-4766-8359-fd8b2f7ad70c'	System	20 Sep 2020 16:07:43
User entered 'None (0)'	System	20 Sep 2020 16:07:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:13', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9db3914b-407d-4766-8359-fd8b2f7ad70c'	System	20 Sep 2020 16:07:43
User entered 'None (0)'	System	20 Sep 2020 16:07:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:16', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9db3914b-407d-4766-8359-fd8b2f7ad70c'	System	20 Sep 2020 16:07:43
User entered 'None (0)'	System	20 Sep 2020 16:07:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:19', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9db3914b-407d-4766-8359-fd8b2f7ad70c'	System	20 Sep 2020 16:07:43
User entered 'None (0)'	System	20 Sep 2020 16:07:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:23', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9db3914b-407d-4766-8359-fd8b2f7ad70c'	System	20 Sep 2020 16:07:43
User entered 'None (0)'	System	20 Sep 2020 16:07:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:26', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9db3914b-407d-4766-8359-fd8b2f7ad70c'	System	20 Sep 2020 16:07:43
User entered 'None (0)'	System	20 Sep 2020 16:07:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:30', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9db3914b-407d-4766-8359-fd8b2f7ad70c'	System	20 Sep 2020 16:07:43
User entered 'No (N)'	System	20 Sep 2020 16:07:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-20T12:07:36', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9db3914b-407d-4766-8359-fd8b2f7ad70c'	System	20 Sep 2020 16:07:43
User entered '20 Sep 2020 12:07'	System	20 Sep 2020 16:07:43

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 5'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:20', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b0020b9-ef21-4cd9-ba17-842981b64c8e'	System	21 Sep 2020 16:17:21
User entered 'None (0)'	System	21 Sep 2020 16:17:21

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:23', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b0020b9-ef21-4cd9-ba17-842981b64c8e'	System	21 Sep 2020 16:17:21
User entered 'None (0)'	System	21 Sep 2020 16:17:21

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:25', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b0020b9-ef21-4cd9-ba17-842981b64c8e'	System	21 Sep 2020 16:17:21
User entered 'None (0)'	System	21 Sep 2020 16:17:21

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:28', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b0020b9-ef21-4cd9-ba17-842981b64c8e'	System	21 Sep 2020 16:17:21
User entered 'None (0)'	System	21 Sep 2020 16:17:21

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:30', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b0020b9-ef21-4cd9-ba17-842981b64c8e'	System	21 Sep 2020 16:17:21
User entered 'None (0)'	System	21 Sep 2020 16:17:21

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:33', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b0020b9-ef21-4cd9-ba17-842981b64c8e'	System	21 Sep 2020 16:17:21
User entered 'None (0)'	System	21 Sep 2020 16:17:21

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:36', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b0020b9-ef21-4cd9-ba17-842981b64c8e'	System	21 Sep 2020 16:17:21
User entered 'No (N)'	System	21 Sep 2020 16:17:21

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-21T12:02:44', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b0020b9-ef21-4cd9-ba17-842981b64c8e'	System	21 Sep 2020 16:17:21
User entered '21 Sep 2020 12:02'	System	21 Sep 2020 16:17:21

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 6'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:15:57', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2ae271cc-5d98-46c1-828a-944d33bf9d01'	System	22 Sep 2020 21:16:27
User entered 'None (0)'	System	22 Sep 2020 21:16:27

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:16:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2ae271cc-5d98-46c1-828a-944d33bf9d01'	System	22 Sep 2020 21:16:27
User entered 'None (0)'	System	22 Sep 2020 21:16:27

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:16:05', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2ae271cc-5d98-46c1-828a-944d33bf9d01'	System	22 Sep 2020 21:16:27
User entered 'None (0)'	System	22 Sep 2020 21:16:27

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:16:07', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2ae271cc-5d98-46c1-828a-944d33bf9d01'	System	22 Sep 2020 21:16:27
User entered 'None (0)'	System	22 Sep 2020 21:16:27

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:16:12', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2ae271cc-5d98-46c1-828a-944d33bf9d01'	System	22 Sep 2020 21:16:27
User entered 'None (0)'	System	22 Sep 2020 21:16:27

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:16:18', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2ae271cc-5d98-46c1-828a-944d33bf9d01'	System	22 Sep 2020 21:16:27
User entered 'None (0)'	System	22 Sep 2020 21:16:27

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:16:21', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2ae271cc-5d98-46c1-828a-944d33bf9d01'	System	22 Sep 2020 21:16:27
User entered 'No (N)'	System	22 Sep 2020 21:16:27

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-22T17:16:26', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2ae271cc-5d98-46c1-828a-944d33bf9d01'	System	22 Sep 2020 21:16:27
User entered '22 Sep 2020 17:16'	System	22 Sep 2020 21:16:27

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 7'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:30', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea5d1ca1-96a5-46fa-b1d3-f3bbf379f16d' User entered 'None (0)'	System	23 Sep 2020 17:26:58
	System	23 Sep 2020 17:26:58

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:32', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea5d1ca1-96a5-46fa-b1d3-f3bbf379f16d' User entered 'None (0)'	System	23 Sep 2020 17:26:58
	System	23 Sep 2020 17:26:58

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:48', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea5d1ca1-96a5-46fa-b1d3-f3bbf379f16d' User entered 'None (0)'	System	23 Sep 2020 17:26:58
	System	23 Sep 2020 17:26:58

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:36', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea5d1ca1-96a5-46fa-b1d3-f3bbf379f16d' User entered 'None (0)'	System	23 Sep 2020 17:26:58
	System	23 Sep 2020 17:26:58

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:38', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea5d1ca1-96a5-46fa-b1d3-f3bbf379f16d' User entered 'None (0)'	System	23 Sep 2020 17:26:58
	System	23 Sep 2020 17:26:58

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:40', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea5d1ca1-96a5-46fa-b1d3-f3bbf379f16d' User entered 'None (0)'	System	23 Sep 2020 17:26:58
	System	23 Sep 2020 17:26:58

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:43', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea5d1ca1-96a5-46fa-b1d3-f3bbf379f16d'	System	23 Sep 2020 17:26:58
User entered 'No (N)'	System	23 Sep 2020 17:26:58

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-09-23T13:26:51', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ea5d1ca1-96a5-46fa-b1d3-f3bbf379f16d' User entered '23 Sep 2020 13:26'	System	23 Sep 2020 17:26:58
	System	23 Sep 2020 17:26:58

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:46:53

US3222611

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:31:00
	(b) (4)	

US3222611

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '24 Sep 2020'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:31:00

US3222611

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:31:00

US3222611

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:31:00

US3222611

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:31:10

US3222611

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '1'	System	09 Oct 2020 13:31:10

US3222611

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:32:14
	(b) (4)	

US3222611

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered '01 Oct 2020' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 16:35:11
User entered '1 Oct 2020'	Crystal Paccione (b) (4) (b) (4)	09 Oct 2020 13:32:14

US3222611

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:32:14

US3222611

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:32:14

US3222611

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:32:21

US3222611

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '1'	System	09 Oct 2020 13:32:21

US3222611

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	09 Oct 2020 13:32:33

US3222611

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '8 Oct 2020'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:32:33

US3222611

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:32:33

US3222611

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:32:33

US3222611

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	09 Oct 2020 13:32:37

US3222611

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '1'	System	09 Oct 2020 13:32:37

US3222611

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	15 Oct 2020 14:31:30
	(b) (4)	

US3222611

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '15 Oct 2020'	(b) (4) Jennifer Dittman (b) (4)	15 Oct 2020 14:31:30
	(b) (4)	

US3222611

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	15 Oct 2020 14:31:30

US3222611

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'VISIT2'	System	15 Oct 2020 14:31:30

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User accepted default value 'Pre-Dose (PREDOSE)'	Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	15 Oct 2020 16:06:07
	(b) (4)	

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '15 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '09:00'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '15 Oct 2020 09:00'	System	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '36.7' C	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Oral (Oral)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '76'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'bpm'	System	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '16'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'breaths/min'	System	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '120'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'mmHg'	System	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '73'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'mmHg'	System	15 Oct 2020 16:06:07

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User accepted default value 'Post-Dose (POSTDOSE)'	Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '15 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '10:43'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '15 Oct 2020 10:43'	System	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '36.7' C	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Oral (Oral)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '77'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'bpm'	System	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '16'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'breaths/min'	System	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '127'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'mmHg'	System	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '83'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'mmHg'	System	15 Oct 2020 16:29:02

US3222611

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:09

US3222611

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:09

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	15 Oct 2020 14:32:10

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Jennifer Dittman (b) (4)	15 Oct 2020 14:32:10
	(b) (4)	

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Jennifer Dittman (b) (4)	15 Oct 2020 14:32:10

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 14:32:10

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '15 Oct 2020'	(b) (4) Jennifer Dittman (b) (4) (b) (4)	15 Oct 2020 14:32:10

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '10:12'	(b) (4) Jennifer Dittman (b) (4)	15 Oct 2020 14:32:10

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '15 Oct 2020 10:12'	System	15 Oct 2020 14:32:10

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) Jennifer Dittman (b) (4)	15 Oct 2020 14:32:10
	(b) (4)	

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'ONCE'	System	15 Oct 2020 14:32:10

US3222611

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 14:32:10

US3222611

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	15 Oct 2020 16:29:28

US3222611

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '15 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:28

US3222611

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '09:30'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:28

US3222611

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '15 Oct 2020 09:30'	System	15 Oct 2020 16:29:28

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:09:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '15 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:49

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:49

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	15 Oct 2020 16:29:49

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '09:35'	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:49

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '15 Oct 2020 09:35'	System	15 Oct 2020 16:29:49

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:49

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	15 Oct 2020 16:29:49
	(b) (4)	

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	15 Oct 2020 16:29:49

US3222611

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered empty.	System	15 Oct 2020 16:29:49

US3222611

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	15 Oct 2020 14:32:16

US3222611

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '1'	System	15 Oct 2020 14:32:16

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:34:04', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '10398304-8008-468f-ab8c-006f09eb4d9e'	System	15 Oct 2020 14:34:30
User entered 'Yes (Y)'	System	15 Oct 2020 14:34:30

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:34:15', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '10398304-8008-468f-ab8c-006f09eb4d9e'	System	15 Oct 2020 14:34:30
User entered '98.0'	System	15 Oct 2020 14:34:30

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:34:23', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '10398304-8008-468f-ab8c-006f09eb4d9e'	System	15 Oct 2020 14:34:30
User entered 'No (N)'	System	15 Oct 2020 14:34:30

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:34:31', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '10398304-8008-468f-ab8c-006f09eb4d9e' User entered '15 Oct 2020 10:34'	System	15 Oct 2020 14:34:30
	System	15 Oct 2020 14:34:30

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '15 Oct 2020 10:32'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '15 Oct 2020 13:02'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:30:59', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e830496f-7183-4035-b712-0521f520a51a'	System	15 Oct 2020 18:31:16
User entered 'Yes (Y)'	System	15 Oct 2020 18:31:16

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:06', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e830496f-7183-4035-b712-0521f520a51a'	System	15 Oct 2020 18:31:16
User entered '98.0'	System	15 Oct 2020 18:31:16

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:12', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e830496f-7183-4035-b712-0521f520a51a'	System	15 Oct 2020 18:31:16
User entered 'No (N)'	System	15 Oct 2020 18:31:16

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:17', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e830496f-7183-4035-b712-0521f520a51a'	System	15 Oct 2020 18:31:16
User entered '15 Oct 2020 14:31'	System	15 Oct 2020 18:31:16

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '15 Oct 2020 13:57'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 2'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:10:42', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '04814f9d-3363-4587-b8a8-4825ec6c9b68'	System	16 Oct 2020 22:11:12
User entered 'Yes (Y)'	System	16 Oct 2020 22:11:12

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:10:51', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '04814f9d-3363-4587-b8a8-4825ec6c9b68'	System	16 Oct 2020 22:11:12
User entered '98.2'	System	16 Oct 2020 22:11:12

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:10:54', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '04814f9d-3363-4587-b8a8-4825ec6c9b68'	System	16 Oct 2020 22:11:12
User entered 'No (N)'	System	16 Oct 2020 22:11:12

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:01', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '04814f9d-3363-4587-b8a8-4825ec6c9b68'	System	16 Oct 2020 22:11:12
User entered '16 Oct 2020 18:11'	System	16 Oct 2020 22:11:12

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 3'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:41:39', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '99c38430-4e36-4a68-8e14-4d5446fe61e7'	System	18 Oct 2020 02:42:00
User entered 'Yes (Y)'	System	18 Oct 2020 02:42:00

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:41:47', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '99c38430-4e36-4a68-8e14-4d5446fe61e7'	System	18 Oct 2020 02:42:00
User entered '98.1'	System	18 Oct 2020 02:42:00

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:41:53', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '99c38430-4e36-4a68-8e14-4d5446fe61e7'	System	18 Oct 2020 02:42:00
User entered 'No (N)'	System	18 Oct 2020 02:42:00

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:41:56', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '99c38430-4e36-4a68-8e14-4d5446fe61e7'	System	18 Oct 2020 02:42:00
User entered '17 Oct 2020 22:41'	System	18 Oct 2020 02:42:00

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 4'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:35:38', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e57d81c4-92de-4cb9-a9d4-c3dd15c4feb0'	System	18 Oct 2020 22:35:54
User entered 'Yes (Y)'	System	18 Oct 2020 22:35:54

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:35:44', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e57d81c4-92de-4cb9-a9d4-c3dd15c4feb0'	System	18 Oct 2020 22:35:54
User entered '98.0'	System	18 Oct 2020 22:35:54

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:35:50', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e57d81c4-92de-4cb9-a9d4-c3dd15c4feb0'	System	18 Oct 2020 22:35:54
User entered 'No (N)'	System	18 Oct 2020 22:35:54

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:35:53', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e57d81c4-92de-4cb9-a9d4-c3dd15c4feb0' User entered '18 Oct 2020 18:35'	System	18 Oct 2020 22:35:54
	System	18 Oct 2020 22:35:54

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 5'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:47:18', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '72adabc1-938d-48d3-bf9a-1ae7a0083c8d'	System	19 Oct 2020 16:53:17
User entered 'Yes (Y)'	System	19 Oct 2020 16:53:17

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:47:24', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '72adabc1-938d-48d3-bf9a-1ae7a0083c8d' User entered '98.1'	System	19 Oct 2020 16:53:17
	System	19 Oct 2020 16:53:17

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:47:27', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '72adabc1-938d-48d3-bf9a-1ae7a0083c8d'	System	19 Oct 2020 16:53:17
User entered 'No (N)'	System	19 Oct 2020 16:53:17

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:47:31', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '72adabc1-938d-48d3-bf9a-1ae7a0083c8d' User entered '19 Oct 2020 12:47'	System	19 Oct 2020 16:53:17
	System	19 Oct 2020 16:53:17

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 6'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:44:05', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a4bd5432-bb30-463c-9b87-52f421c56b8a'	System	20 Oct 2020 18:45:02
User entered 'Yes (Y)'	System	20 Oct 2020 18:45:02

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:44:13', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a4bd5432-bb30-463c-9b87-52f421c56b8a'	System	20 Oct 2020 18:45:02
User entered '98.2'	System	20 Oct 2020 18:45:02

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:44:17', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a4bd5432-bb30-463c-9b87-52f421c56b8a'	System	20 Oct 2020 18:45:02
User entered 'No (N)'	System	20 Oct 2020 18:45:02

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:44:59', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a4bd5432-bb30-463c-9b87-52f421c56b8a' User entered '20 Oct 2020 14:44'	System	20 Oct 2020 18:45:02
	System	20 Oct 2020 18:45:02

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 7'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:24:20', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '80391bc2-6d44-480c-b167-223a5fb9178c'	System	21 Oct 2020 22:24:41
User entered 'Yes (Y)'	System	21 Oct 2020 22:24:41

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:24:29', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '80391bc2-6d44-480c-b167-223a5fb9178c'	System	21 Oct 2020 22:24:41
User entered '97.8'	System	21 Oct 2020 22:24:41

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:24:32', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '80391bc2-6d44-480c-b167-223a5fb9178c'	System	21 Oct 2020 22:24:41
User entered 'No (N)'	System	21 Oct 2020 22:24:41

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:24:36', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '80391bc2-6d44-480c-b167-223a5fb9178c'	System	21 Oct 2020 22:24:41
User entered '21 Oct 2020 18:24'	System	21 Oct 2020 22:24:41

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:34:40', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd6cd43b0-0d09-4dd0-8511-854e6f4d98b2'	System	15 Oct 2020 14:35:08
User entered 'None (1)'	System	15 Oct 2020 14:35:08

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:34:46', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd6cd43b0-0d09-4dd0-8511-854e6f4d98b2'	System	15 Oct 2020 14:35:08
User entered 'No (N)'	System	15 Oct 2020 14:35:08

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:34:53', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd6cd43b0-0d09-4dd0-8511-854e6f4d98b2'	System	15 Oct 2020 14:35:08
User entered 'No (N)'	System	15 Oct 2020 14:35:08

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:34:58', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd6cd43b0-0d09-4dd0-8511-854e6f4d98b2'	System	15 Oct 2020 14:35:08
User entered 'None (1)'	System	15 Oct 2020 14:35:08

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:35:03', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'd6cd43b0-0d09-4dd0-8511-854e6f4d98b2'	System	15 Oct 2020 14:35:08
User entered '15 Oct 2020 10:35'	System	15 Oct 2020 14:35:08

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '15 Oct 2020 10:32'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '15 Oct 2020 13:02'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:24', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9a583334-379f-439f-98ab-8a2b54dd7693'	System	15 Oct 2020 18:31:43
User entered 'None (1)'	System	15 Oct 2020 18:31:43

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:29', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9a583334-379f-439f-98ab-8a2b54dd7693'	System	15 Oct 2020 18:31:43
User entered 'No (N)'	System	15 Oct 2020 18:31:43

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:36', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9a583334-379f-439f-98ab-8a2b54dd7693'	System	15 Oct 2020 18:31:43
User entered 'No (N)'	System	15 Oct 2020 18:31:43

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:40', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9a583334-379f-439f-98ab-8a2b54dd7693'	System	15 Oct 2020 18:31:43
User entered 'None (1)'	System	15 Oct 2020 18:31:43

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:44', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9a583334-379f-439f-98ab-8a2b54dd7693'	System	15 Oct 2020 18:31:43
User entered '15 Oct 2020 14:31'	System	15 Oct 2020 18:31:43

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '15 Oct 2020 13:57'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 2'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:07', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ac87f39c-5b56-4539-854b-6bec46cbbe6e'	System	16 Oct 2020 22:11:35
User entered 'None (1)'	System	16 Oct 2020 22:11:35

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:10', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ac87f39c-5b56-4539-854b-6bec46cbbe6e'	System	16 Oct 2020 22:11:35
User entered 'No (N)'	System	16 Oct 2020 22:11:35

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:14', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ac87f39c-5b56-4539-854b-6bec46cbbe6e'	System	16 Oct 2020 22:11:35
User entered 'No (N)'	System	16 Oct 2020 22:11:35

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:20', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ac87f39c-5b56-4539-854b-6bec46cbbe6e'	System	16 Oct 2020 22:11:35
User entered 'None (1)'	System	16 Oct 2020 22:11:35

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:25', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ac87f39c-5b56-4539-854b-6bec46cbbe6e'	System	16 Oct 2020 22:11:35
User entered '16 Oct 2020 18:11'	System	16 Oct 2020 22:11:35

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 3'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:01', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9e8ca394-fec7-45b1-a60f-64c3042f710b'	System	18 Oct 2020 02:42:16
User entered 'None (1)'	System	18 Oct 2020 02:42:16

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:05', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9e8ca394-fec7-45b1-a60f-64c3042f710b'	System	18 Oct 2020 02:42:16
User entered 'No (N)'	System	18 Oct 2020 02:42:16

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:08', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9e8ca394-fec7-45b1-a60f-64c3042f710b'	System	18 Oct 2020 02:42:16
User entered 'No (N)'	System	18 Oct 2020 02:42:16

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:11', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9e8ca394-fec7-45b1-a60f-64c3042f710b'	System	18 Oct 2020 02:42:16
User entered 'None (1)'	System	18 Oct 2020 02:42:16

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:14', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9e8ca394-fec7-45b1-a60f-64c3042f710b' User entered '17 Oct 2020 22:42'	System	18 Oct 2020 02:42:16
	System	18 Oct 2020 02:42:16

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 4'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3d7395ae-23a3-42cc-a614-25b66800f404'	System	18 Oct 2020 22:36:26
User entered 'None (1)'	System	18 Oct 2020 22:36:26

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:14', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3d7395ae-23a3-42cc-a614-25b66800f404'	System	18 Oct 2020 22:36:26
User entered 'No (N)'	System	18 Oct 2020 22:36:26

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:16', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3d7395ae-23a3-42cc-a614-25b66800f404'	System	18 Oct 2020 22:36:26
User entered 'No (N)'	System	18 Oct 2020 22:36:26

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:20', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3d7395ae-23a3-42cc-a614-25b66800f404'	System	18 Oct 2020 22:36:26
User entered 'None (1)'	System	18 Oct 2020 22:36:26

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:24', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3d7395ae-23a3-42cc-a614-25b66800f404'	System	18 Oct 2020 22:36:26
User entered '18 Oct 2020 18:36'	System	18 Oct 2020 22:36:26

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 5'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:47:37', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'be3f4831-eab8-4e76-bb7d-506d2161be69'	System	19 Oct 2020 16:53:27
User entered 'None (1)'	System	19 Oct 2020 16:53:27

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:47:41', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'be3f4831-eab8-4e76-bb7d-506d2161be69'	System	19 Oct 2020 16:53:27
User entered 'No (N)'	System	19 Oct 2020 16:53:27

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:47:46', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'be3f4831-eab8-4e76-bb7d-506d2161be69'	System	19 Oct 2020 16:53:27
User entered 'No (N)'	System	19 Oct 2020 16:53:27

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:47:49', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'be3f4831-eab8-4e76-bb7d-506d2161be69'	System	19 Oct 2020 16:53:27
User entered 'None (1)'	System	19 Oct 2020 16:53:27

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:47:53', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'be3f4831-eab8-4e76-bb7d-506d2161be69' User entered '19 Oct 2020 12:47'	System	19 Oct 2020 16:53:27
	System	19 Oct 2020 16:53:27

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 6'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:38', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'b1a4a825-a4c2-4638-91c4-47b24d737b99'	System	20 Oct 2020 18:43:56
User entered 'None (1)'	System	20 Oct 2020 18:43:56

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:42', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'b1a4a825-a4c2-4638-91c4-47b24d737b99'	System	20 Oct 2020 18:43:56
User entered 'No (N)'	System	20 Oct 2020 18:43:56

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:46', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'b1a4a825-a4c2-4638-91c4-47b24d737b99'	System	20 Oct 2020 18:43:56
User entered 'No (N)'	System	20 Oct 2020 18:43:56

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:50', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'b1a4a825-a4c2-4638-91c4-47b24d737b99'	System	20 Oct 2020 18:43:56
User entered 'None (1)'	System	20 Oct 2020 18:43:56

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:53', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'b1a4a825-a4c2-4638-91c4-47b24d737b99'	System	20 Oct 2020 18:43:56
User entered '20 Oct 2020 14:43'	System	20 Oct 2020 18:43:56

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 7'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:24:42', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e89298e5-5003-46af-9100-2d9e379debba'	System	21 Oct 2020 22:25:00
User entered 'None (1)'	System	21 Oct 2020 22:25:00

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:24:45', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e89298e5-5003-46af-9100-2d9e379debba'	System	21 Oct 2020 22:25:00
User entered 'No (N)'	System	21 Oct 2020 22:25:00

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:24:49', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e89298e5-5003-46af-9100-2d9e379debba'	System	21 Oct 2020 22:25:00
User entered 'No (N)'	System	21 Oct 2020 22:25:00

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

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 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:24:54', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e89298e5-5003-46af-9100-2d9e379debba'	System	21 Oct 2020 22:25:00
User entered 'None (1)'	System	21 Oct 2020 22:25:00

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:24:59', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e89298e5-5003-46af-9100-2d9e379debba'	System	21 Oct 2020 22:25:00
User entered '21 Oct 2020 18:24'	System	21 Oct 2020 22:25:00

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:35:13', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '12391b70-1947-416d-ae3f-8bbeff74a827'	System	15 Oct 2020 14:36:10
User entered 'None (0)'	System	15 Oct 2020 14:36:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:35:16', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '12391b70-1947-416d-ae3f-8bbeff74a827'	System	15 Oct 2020 14:36:10
User entered 'None (0)'	System	15 Oct 2020 14:36:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:35:23', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '12391b70-1947-416d-ae3f-8bbeff74a827'	System	15 Oct 2020 14:36:10
User entered 'None (0)'	System	15 Oct 2020 14:36:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:35:31', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '12391b70-1947-416d-ae3f-8bbeff74a827'	System	15 Oct 2020 14:36:10
User entered 'None (0)'	System	15 Oct 2020 14:36:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:35:44', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '12391b70-1947-416d-ae3f-8bbeff74a827'	System	15 Oct 2020 14:36:10
User entered 'None (0)'	System	15 Oct 2020 14:36:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:35:55', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '12391b70-1947-416d-ae3f-8bbeff74a827'	System	15 Oct 2020 14:36:10
User entered 'None (0)'	System	15 Oct 2020 14:36:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:36:02', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '12391b70-1947-416d-ae3f-8bbeff74a827'	System	15 Oct 2020 14:36:10
User entered 'No (N)'	System	15 Oct 2020 14:36:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T10:36:08', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '12391b70-1947-416d-ae3f-8bbeff74a827'	System	15 Oct 2020 14:36:10
User entered '15 Oct 2020 10:36'	System	15 Oct 2020 14:36:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '15 Oct 2020 10:32'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '15 Oct 2020 13:02'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:51', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '78013d35-2045-4398-97b7-91d0f86f9ef3'	System	15 Oct 2020 18:32:27
User entered 'None (0)'	System	15 Oct 2020 18:32:27

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:31:54', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '78013d35-2045-4398-97b7-91d0f86f9ef3'	System	15 Oct 2020 18:32:27
User entered 'None (0)'	System	15 Oct 2020 18:32:27

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:32:06', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '78013d35-2045-4398-97b7-91d0f86f9ef3'	System	15 Oct 2020 18:32:27
User entered 'None (0)'	System	15 Oct 2020 18:32:27

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:32:10', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '78013d35-2045-4398-97b7-91d0f86f9ef3'	System	15 Oct 2020 18:32:27
User entered 'None (0)'	System	15 Oct 2020 18:32:27

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:32:14', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '78013d35-2045-4398-97b7-91d0f86f9ef3'	System	15 Oct 2020 18:32:27
User entered 'None (0)'	System	15 Oct 2020 18:32:27

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:32:18', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '78013d35-2045-4398-97b7-91d0f86f9ef3'	System	15 Oct 2020 18:32:27
User entered 'None (0)'	System	15 Oct 2020 18:32:27

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:32:25', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '78013d35-2045-4398-97b7-91d0f86f9ef3'	System	15 Oct 2020 18:32:27
User entered 'No (N)'	System	15 Oct 2020 18:32:27

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-15T14:32:29', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '78013d35-2045-4398-97b7-91d0f86f9ef3'	System	15 Oct 2020 18:32:27
User entered '15 Oct 2020 14:32'	System	15 Oct 2020 18:32:27

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '15 Oct 2020 13:57'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 2'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:32', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'aa13eae1-28eb-43a3-b231-d58dbe0b14f5'	System	16 Oct 2020 22:12:32
User entered 'None (0)'	System	16 Oct 2020 22:12:32

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:39', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'aa13eae1-28eb-43a3-b231-d58dbe0b14f5'	System	16 Oct 2020 22:12:32
User entered 'None (0)'	System	16 Oct 2020 22:12:32

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:42', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'aa13eae1-28eb-43a3-b231-d58dbe0b14f5'	System	16 Oct 2020 22:12:32
User entered 'None (0)'	System	16 Oct 2020 22:12:32

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:11:49', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'aa13eae1-28eb-43a3-b231-d58dbe0b14f5'	System	16 Oct 2020 22:12:32
User entered 'None (0)'	System	16 Oct 2020 22:12:32

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:12:02', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'aa13eae1-28eb-43a3-b231-d58dbe0b14f5'	System	16 Oct 2020 22:12:32
User entered 'None (0)'	System	16 Oct 2020 22:12:32

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:12:05', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'aa13eae1-28eb-43a3-b231-d58dbe0b14f5'	System	16 Oct 2020 22:12:32
User entered 'None (0)'	System	16 Oct 2020 22:12:32

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:12:11', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'aa13eae1-28eb-43a3-b231-d58dbe0b14f5'	System	16 Oct 2020 22:12:32
User entered 'No (N)'	System	16 Oct 2020 22:12:32

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-16T18:12:20', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'aa13eae1-28eb-43a3-b231-d58dbe0b14f5'	System	16 Oct 2020 22:12:32
User entered '16 Oct 2020 18:12'	System	16 Oct 2020 22:12:32

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 3'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:19', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7b82c604-45dd-4ff1-ae9d-a0c99c362214'	System	18 Oct 2020 02:42:44
User entered 'None (0)'	System	18 Oct 2020 02:42:44

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:21', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7b82c604-45dd-4ff1-ae9d-a0c99c362214'	System	18 Oct 2020 02:42:44
User entered 'None (0)'	System	18 Oct 2020 02:42:44

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:24', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7b82c604-45dd-4ff1-ae9d-a0c99c362214'	System	18 Oct 2020 02:42:44
User entered 'None (0)'	System	18 Oct 2020 02:42:44

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:26', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7b82c604-45dd-4ff1-ae9d-a0c99c362214'	System	18 Oct 2020 02:42:44
User entered 'None (0)'	System	18 Oct 2020 02:42:44

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:29', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7b82c604-45dd-4ff1-ae9d-a0c99c362214'	System	18 Oct 2020 02:42:44
User entered 'None (0)'	System	18 Oct 2020 02:42:44

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:32', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7b82c604-45dd-4ff1-ae9d-a0c99c362214'	System	18 Oct 2020 02:42:44
User entered 'None (0)'	System	18 Oct 2020 02:42:44

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:37', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7b82c604-45dd-4ff1-ae9d-a0c99c362214'	System	18 Oct 2020 02:42:44
User entered 'No (N)'	System	18 Oct 2020 02:42:44

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-17T22:42:42', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '7b82c604-45dd-4ff1-ae9d-a0c99c362214'	System	18 Oct 2020 02:42:44
User entered '17 Oct 2020 22:42'	System	18 Oct 2020 02:42:44

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 4'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:29', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '683b053d-3bbb-4478-8d36-9ad794cc1b64'	System	18 Oct 2020 22:36:55
User entered 'None (0)'	System	18 Oct 2020 22:36:55

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:31', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '683b053d-3bbb-4478-8d36-9ad794cc1b64'	System	18 Oct 2020 22:36:55
User entered 'None (0)'	System	18 Oct 2020 22:36:55

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:33', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '683b053d-3bbb-4478-8d36-9ad794cc1b64'	System	18 Oct 2020 22:36:55
User entered 'None (0)'	System	18 Oct 2020 22:36:55

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:36', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '683b053d-3bbb-4478-8d36-9ad794cc1b64'	System	18 Oct 2020 22:36:55
User entered 'None (0)'	System	18 Oct 2020 22:36:55

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:38', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '683b053d-3bbb-4478-8d36-9ad794cc1b64'	System	18 Oct 2020 22:36:55
User entered 'None (0)'	System	18 Oct 2020 22:36:55

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:41', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '683b053d-3bbb-4478-8d36-9ad794cc1b64'	System	18 Oct 2020 22:36:55
User entered 'None (0)'	System	18 Oct 2020 22:36:55

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:46', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '683b053d-3bbb-4478-8d36-9ad794cc1b64'	System	18 Oct 2020 22:36:55
User entered 'No (N)'	System	18 Oct 2020 22:36:55

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-18T18:36:55', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '683b053d-3bbb-4478-8d36-9ad794cc1b64' User entered '18 Oct 2020 18:36'	System	18 Oct 2020 22:36:55
	System	18 Oct 2020 22:36:55

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 5'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:48:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '17305ad2-cf9c-4e47-a725-f20f59701237'	System	19 Oct 2020 16:53:43
User entered 'None (0)'	System	19 Oct 2020 16:53:43

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:48:05', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '17305ad2-cf9c-4e47-a725-f20f59701237'	System	19 Oct 2020 16:53:43
User entered 'None (0)'	System	19 Oct 2020 16:53:43

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:48:08', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '17305ad2-cf9c-4e47-a725-f20f59701237'	System	19 Oct 2020 16:53:43
User entered 'None (0)'	System	19 Oct 2020 16:53:43

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:48:10', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '17305ad2-cf9c-4e47-a725-f20f59701237'	System	19 Oct 2020 16:53:43
User entered 'None (0)'	System	19 Oct 2020 16:53:43

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:48:12', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '17305ad2-cf9c-4e47-a725-f20f59701237'	System	19 Oct 2020 16:53:43
User entered 'None (0)'	System	19 Oct 2020 16:53:43

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:48:15', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '17305ad2-cf9c-4e47-a725-f20f59701237'	System	19 Oct 2020 16:53:43
User entered 'None (0)'	System	19 Oct 2020 16:53:43

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:48:21', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '17305ad2-cf9c-4e47-a725-f20f59701237'	System	19 Oct 2020 16:53:43
User entered 'No (N)'	System	19 Oct 2020 16:53:43

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-19T12:48:31', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '17305ad2-cf9c-4e47-a725-f20f59701237'	System	19 Oct 2020 16:53:43
User entered '19 Oct 2020 12:48'	System	19 Oct 2020 16:53:43

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 6'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:09', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b06e41d-1172-4331-9b47-738e1f9f6a82'	System	20 Oct 2020 18:43:37
User entered 'None (0)'	System	20 Oct 2020 18:43:37

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:11', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b06e41d-1172-4331-9b47-738e1f9f6a82'	System	20 Oct 2020 18:43:37
User entered 'None (0)'	System	20 Oct 2020 18:43:37

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:13', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b06e41d-1172-4331-9b47-738e1f9f6a82'	System	20 Oct 2020 18:43:37
User entered 'None (0)'	System	20 Oct 2020 18:43:37

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:15', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b06e41d-1172-4331-9b47-738e1f9f6a82'	System	20 Oct 2020 18:43:37
User entered 'None (0)'	System	20 Oct 2020 18:43:37

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:18', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b06e41d-1172-4331-9b47-738e1f9f6a82'	System	20 Oct 2020 18:43:37
User entered 'None (0)'	System	20 Oct 2020 18:43:37

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:20', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b06e41d-1172-4331-9b47-738e1f9f6a82'	System	20 Oct 2020 18:43:37
User entered 'None (0)'	System	20 Oct 2020 18:43:37

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:27', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b06e41d-1172-4331-9b47-738e1f9f6a82'	System	20 Oct 2020 18:43:37
User entered 'No (N)'	System	20 Oct 2020 18:43:37

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-20T14:43:33', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9b06e41d-1172-4331-9b47-738e1f9f6a82'	System	20 Oct 2020 18:43:37
User entered '20 Oct 2020 14:43'	System	20 Oct 2020 18:43:37

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
Data entry locked.	System	15 Oct 2020 14:32:10
User entered 'Day 7'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:25:05', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0025a2fc-7b6a-4b52-8108-0cd45fcb8439'	System	21 Oct 2020 22:26:11
User entered 'None (0)'	System	21 Oct 2020 22:26:11

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:25:12', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0025a2fc-7b6a-4b52-8108-0cd45fcb8439'	System	21 Oct 2020 22:26:11
User entered 'None (0)'	System	21 Oct 2020 22:26:11

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:25:25', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0025a2fc-7b6a-4b52-8108-0cd45fcb8439'	System	21 Oct 2020 22:26:11
User entered 'None (0)'	System	21 Oct 2020 22:26:11

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:25:30', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0025a2fc-7b6a-4b52-8108-0cd45fcb8439'	System	21 Oct 2020 22:26:11
User entered 'None (0)'	System	21 Oct 2020 22:26:11

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:25:34', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0025a2fc-7b6a-4b52-8108-0cd45fcb8439'	System	21 Oct 2020 22:26:11
User entered 'None (0)'	System	21 Oct 2020 22:26:11

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:25:38', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0025a2fc-7b6a-4b52-8108-0cd45fcb8439'	System	21 Oct 2020 22:26:11
User entered 'None (0)'	System	21 Oct 2020 22:26:11

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:25:59', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0025a2fc-7b6a-4b52-8108-0cd45fcb8439'	System	21 Oct 2020 22:26:11
User entered 'No (N)'	System	21 Oct 2020 22:26:11

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-10-21T18:26:09', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '0025a2fc-7b6a-4b52-8108-0cd45fcb8439'	System	21 Oct 2020 22:26:11
User entered '21 Oct 2020 18:26'	System	21 Oct 2020 22:26:11

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:32:10

US3222611

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:38:06
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:32:10

US3222611

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	12 Nov 2020 18:53:47
	(b) (4)	

US3222611

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '22 Oct 2020'	(b) (4) douglas winter (b) (4)	12 Nov 2020 18:53:47
	(b) (4)	

US3222611

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) douglas winter (b) (4)	12 Nov 2020 18:53:47

US3222611

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Nov 2020 18:53:47

US3222611

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	12 Nov 2020 18:53:53
	(b) (4)	

US3222611

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'I'	System	12 Nov 2020 18:53:53

US3222611

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	12 Nov 2020 18:54:15
	(b) (4)	

US3222611

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '29 Oct 2020'	(b) (4) douglas winter (b) (4)	12 Nov 2020 18:54:15
	(b) (4)	

US3222611

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Contact Made (CONTACT MADE)'	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:54:15

US3222611

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Nov 2020 18:54:15

US3222611

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	12 Nov 2020 18:54:21
	(b) (4)	

US3222611

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '1'	System	12 Nov 2020 18:54:21

US3222611

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	12 Nov 2020 18:54:34
	(b) (4)	

US3222611

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:25:38
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'PATIENT WAS AN SAE. I DID HIS SAFETY CALL OOW.' (Site from System).	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:55:03
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Nov 2020 18:54:34
User entered '12 Nov 2020'	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:54:34

US3222611

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Contact Made (CONTACT MADE)'	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:54:34

US3222611

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	12 Nov 2020 18:54:34

US3222611

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	12 Nov 2020 18:55:09
	(b) (4)	

US3222611

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '1'	System	12 Nov 2020 18:55:09

US3222611

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:27

US3222611

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '18 Nov 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:27

US3222611

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Clinic (Clinic)'	(b) (4) Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:27

US3222611

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered 'VISIT3'	System	18 Nov 2020 16:45:27

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered empty.	System	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered empty.	System	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered empty.	System	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered empty.	System	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered empty.	System	18 Nov 2020 16:45:43

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08

US3222611

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08

US3222611

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:56

US3222611

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '18 Nov 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:45:56

US3222611

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:46:11

US3222611

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18NOV2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18NOV2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'accession # 1F604724278' (Site from DM).	(b) (4) (b) (4), (b) (6) gail lavine (b) (4) (b) (4)	21 Jan 2021 13:34:53 20 Jan 2021 13:38:09
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18NOV2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:23:18
User entered '18 Nov 2020'	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:46:11

US3222611

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered '10:20'	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 16:46:11

US3222611

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '18 Nov 2020 10:20'	System	18 Nov 2020 16:46:11

US3222611

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	18 Nov 2020 16:46:15

US3222611

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '1'	System	18 Nov 2020 16:46:15

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36
Data entry locked.	System	17 Sep 2020 14:46:53
User entered 'Day 64'	System	17 Sep 2020 14:46:53

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:09:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36
Data entry locked.	System	17 Sep 2020 14:46:53
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 14:46:53

US3222611

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:09:36
Data entry locked.	System	17 Sep 2020 14:46:53
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 14:46:53

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 09:51:17
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'this was a routine follow up to his PCP' (Site from DM).	Crystal Paccione (b) (4)	09 Apr 2021 18:10:31
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 08:24:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-09T08:45:02', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '64182229-e503-42cd-b389-3035d57e43ad'	System	09 Dec 2020 13:46:34
User entered 'Yes (Y)'	System	09 Dec 2020 13:46:34

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-09T08:45:08', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '64182229-e503-42cd-b389-3035d57e43ad'	System	09 Dec 2020 13:46:34
User entered 'No (N)'	System	09 Dec 2020 13:46:34

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-09T08:45:16', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '64182229-e503-42cd-b389-3035d57e43ad'	System	09 Dec 2020 13:46:34
User entered 'No (N)'	System	09 Dec 2020 13:46:34

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-09T08:45:31', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '64182229-e503-42cd-b389-3035d57e43ad'	System	09 Dec 2020 13:46:34
User entered 'Yes (Y)'	System	09 Dec 2020 13:46:34

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-09T08:45:46', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '64182229-e503-42cd-b389-3035d57e43ad'	System	09 Dec 2020 13:46:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Dec 2020 13:46:34

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-09T08:46:22', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '64182229-e503-42cd-b389-3035d57e43ad' User entered '09 Dec 2020 08:46:22'	System	09 Dec 2020 13:46:34
	System	09 Dec 2020 13:46:34

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-12T06:45:17', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a6985aac-7b71-4ec7-b8d5-13c2fb7b185c'	System	12 Dec 2020 11:45:37
User entered 'No (N)'	System	12 Dec 2020 11:45:37

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-12T06:45:21', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a6985aac-7b71-4ec7-b8d5-13c2fb7b185c'	System	12 Dec 2020 11:45:37
User entered 'No (N)'	System	12 Dec 2020 11:45:37

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-12T06:45:32', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'a6985aac-7b71-4ec7-b8d5-13c2fb7b185c'	System	12 Dec 2020 11:45:37
User entered '12 Dec 2020 06:45:32'	System	12 Dec 2020 11:45:37

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-21T08:27:55', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ca026ba4-3eaa-4d9c-825e-7cf5cedcf505'	System	21 Dec 2020 17:28:30
User entered 'No (N)'	System	21 Dec 2020 17:28:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-21T08:27:02', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ca026ba4-3eaa-4d9c-825e-7cf5cedcf505'	System	21 Dec 2020 17:28:30
User entered 'No (N)'	System	21 Dec 2020 17:28:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-21T08:28:25', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'ca026ba4-3eaa-4d9c-825e-7cf5cedcf505'	System	21 Dec 2020 17:28:30
User entered '21 Dec 2020 08:28:25'	System	21 Dec 2020 17:28:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-26T12:23:11', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c816139-9cd4-46e1-acda-4e7b1f3310a0'	System	26 Dec 2020 21:23:43
User entered 'No (N)'	System	26 Dec 2020 21:23:43

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-26T12:23:18', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c816139-9cd4-46e1-acda-4e7b1f3310a0'	System	26 Dec 2020 21:23:43
User entered 'No (N)'	System	26 Dec 2020 21:23:43

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2020-12-26T12:23:38', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '3c816139-9cd4-46e1-acda-4e7b1f3310a0'	System	26 Dec 2020 21:23:43
User entered '26 Dec 2020 12:23:38'	System	26 Dec 2020 21:23:43

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-03T21:04:02', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f125a526-1e97-4ffb-979a-5dd6068a27b8'	System	04 Jan 2021 06:05:09
User entered 'No (N)'	System	04 Jan 2021 06:05:09

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-03T21:04:21', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f125a526-1e97-4ffb-979a-5dd6068a27b8'	System	04 Jan 2021 06:05:09
User entered 'No (N)'	System	04 Jan 2021 06:05:09

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-03T21:05:03', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f125a526-1e97-4ffb-979a-5dd6068a27b8' User entered '03 Jan 2021 21:05:03'	System	04 Jan 2021 06:05:09

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-12T16:49:32', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'c3a59ea1-1e81-4576-bbb2-b29771a716b5'	System	12 Jan 2021 21:49:56
User entered 'No (N)'	System	12 Jan 2021 21:49:56

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-12T16:49:40', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'c3a59ea1-1e81-4576-bbb2-b29771a716b5'	System	12 Jan 2021 21:49:56
User entered 'No (N)'	System	12 Jan 2021 21:49:56

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-12T16:49:55', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'c3a59ea1-1e81-4576-bbb2-b29771a716b5'	System	12 Jan 2021 21:49:56
User entered '12 Jan 2021 16:49:55'	System	12 Jan 2021 21:49:56

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-17T10:53:38', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f8dd2770-dfa2-460c-bd26-995457f8ba0a'	System	17 Jan 2021 15:53:55
User entered 'No (N)'	System	17 Jan 2021 15:53:55

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-17T10:53:45', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f8dd2770-dfa2-460c-bd26-995457f8ba0a'	System	17 Jan 2021 15:53:55
User entered 'No (N)'	System	17 Jan 2021 15:53:55

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-17T10:53:51', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f8dd2770-dfa2-460c-bd26-995457f8ba0a'	System	17 Jan 2021 15:53:55
User entered '17 Jan 2021 10:53:51'	System	17 Jan 2021 15:53:55

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-23T12:36:40', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '84526249-2f7e-4dea-8bdd-e0ea1cb65430'	System	23 Jan 2021 17:37:00
User entered 'No (N)'	System	23 Jan 2021 17:37:00

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-23T12:36:46', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '84526249-2f7e-4dea-8bdd-e0ea1cb65430'	System	23 Jan 2021 17:37:00
User entered 'No (N)'	System	23 Jan 2021 17:37:00

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-23T12:36:57', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '84526249-2f7e-4dea-8bdd-e0ea1cb65430' User entered '23 Jan 2021 12:36:57'	System	23 Jan 2021 17:37:00

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-30T11:22:36', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2c3d5464-48a5-4948-a8c8-adc430ee78e7'	System	30 Jan 2021 16:22:50
User entered 'No (N)'	System	30 Jan 2021 16:22:50

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-30T11:22:41', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2c3d5464-48a5-4948-a8c8-adc430ee78e7'	System	30 Jan 2021 16:22:50
User entered 'No (N)'	System	30 Jan 2021 16:22:50

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-01-30T11:22:47', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2c3d5464-48a5-4948-a8c8-adc430ee78e7'	System	30 Jan 2021 16:22:50
User entered '30 Jan 2021 11:22:47'	System	30 Jan 2021 16:22:50

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-10T18:25:25', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '4eb7d6c1-4f35-447d-a94c-db35201e39da'	System	10 Feb 2021 23:25:42
User entered 'No (N)'	System	10 Feb 2021 23:25:42

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-10T18:25:34', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '4eb7d6c1-4f35-447d-a94c-db35201e39da'	System	10 Feb 2021 23:25:42
User entered 'No (N)'	System	10 Feb 2021 23:25:42

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-10T18:25:39', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '4eb7d6c1-4f35-447d-a94c-db35201e39da'	System	10 Feb 2021 23:25:42
User entered '10 Feb 2021 18:25:39'	System	10 Feb 2021 23:25:42

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-13T21:37:42', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '8b6d2970-befb-4f2c-a604-d7a339365376'	System	14 Feb 2021 02:38:00
User entered 'No (N)'	System	14 Feb 2021 02:38:00

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-13T21:37:50', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '8b6d2970-befb-4f2c-a604-d7a339365376'	System	14 Feb 2021 02:38:00
User entered 'No (N)'	System	14 Feb 2021 02:38:00

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-13T21:37:56', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '8b6d2970-befb-4f2c-a604-d7a339365376'	System	14 Feb 2021 02:38:00
User entered '13 Feb 2021 21:37:56'	System	14 Feb 2021 02:38:00

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-24T19:28:44-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '6ea8492b-2636-485b-a87d-c9567071999e'	System	25 Feb 2021 00:32:13
User entered 'No (N)'	System	25 Feb 2021 00:32:13

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-24T19:28:50-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '6ea8492b-2636-485b-a87d-c9567071999e'	System	25 Feb 2021 00:32:13
User entered 'No (N)'	System	25 Feb 2021 00:32:13

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-24T19:28:57-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '6ea8492b-2636-485b-a87d-c9567071999e' User entered '24 Feb 2021 19:28:57'	System	25 Feb 2021 00:32:13

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-27T09:12:12-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f9638f1a-18df-44ac-ae5-974a659f5b27'	System	27 Feb 2021 14:12:28
User entered 'No (N)'	System	27 Feb 2021 14:12:28

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-27T09:12:17-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f9638f1a-18df-44ac-ae5-974a659f5b27'	System	27 Feb 2021 14:12:28
User entered 'No (N)'	System	27 Feb 2021 14:12:28

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-27T09:12:23-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'f9638f1a-18df-44ac-ae5-974a659f5b27'	System	27 Feb 2021 14:12:28
User entered '27 Feb 2021 09:12:23'	System	27 Feb 2021 14:12:28

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-07T12:52:43-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '95cf5560-d2bb-4b9f-b86d-6544ec4bf95e'	System	07 Mar 2021 17:52:57
User entered 'No (N)'	System	07 Mar 2021 17:52:57

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-07T12:52:47-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '95cf5560-d2bb-4b9f-b86d-6544ec4bf95e'	System	07 Mar 2021 17:52:57
User entered 'No (N)'	System	07 Mar 2021 17:52:57

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-07T12:52:54-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '95cf5560-d2bb-4b9f-b86d-6544ec4bf95e' User entered '07 Mar 2021 12:52:54'	System	07 Mar 2021 17:52:57
	System	07 Mar 2021 17:52:57

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-13T07:39:09-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e634ecf7-3b7c-4b85-860f-09c8490ae460'	System	13 Mar 2021 12:39:27
User entered 'No (N)'	System	13 Mar 2021 12:39:27

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-13T07:39:20-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e634ecf7-3b7c-4b85-860f-09c8490ae460'	System	13 Mar 2021 12:39:27
User entered 'No (N)'	System	13 Mar 2021 12:39:27

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-13T07:39:26-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'e634ecf7-3b7c-4b85-860f-09c8490ae460'	System	13 Mar 2021 12:39:27
User entered '13 Mar 2021 07:39:26'	System	13 Mar 2021 12:39:27

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-21T12:56:11-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'c6486952-c154-4842-b1bc-e2881a7c5c59'	System	21 Mar 2021 16:56:27
User entered 'No (N)'	System	21 Mar 2021 16:56:27

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-21T12:56:17-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'c6486952-c154-4842-b1bc-e2881a7c5c59'	System	21 Mar 2021 16:56:27
User entered 'No (N)'	System	21 Mar 2021 16:56:27

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-21T12:56:21-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'c6486952-c154-4842-b1bc-e2881a7c5c59'	System	21 Mar 2021 16:56:27
User entered '21 Mar 2021 12:56:21'	System	21 Mar 2021 16:56:27

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-28T07:14:57-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'acf7b332-f279-4034-9e23-e476679f0670'	System	28 Mar 2021 11:15:20
User entered 'No (N)'	System	28 Mar 2021 11:15:20

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-28T07:15:04-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'acf7b332-f279-4034-9e23-e476679f0670'	System	28 Mar 2021 11:15:20
User entered 'No (N)'	System	28 Mar 2021 11:15:20

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-03-28T07:15:17-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'acf7b332-f279-4034-9e23-e476679f0670'	System	28 Mar 2021 11:15:20
User entered '28 Mar 2021 07:15:17'	System	28 Mar 2021 11:15:20

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-06T17:03:19-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '622bda9c-9bf8-4220-991f-989c35736c5d'	System	06 Apr 2021 21:04:30
User entered 'No (N)'	System	06 Apr 2021 21:04:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-06T17:03:30-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '622bda9c-9bf8-4220-991f-989c35736c5d'	System	06 Apr 2021 21:04:30
User entered 'Yes (Y)'	System	06 Apr 2021 21:04:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-06T17:04:00-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '622bda9c-9bf8-4220-991f-989c35736c5d'	System	06 Apr 2021 21:04:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Apr 2021 21:04:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-06T17:04:13-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '622bda9c-9bf8-4220-991f-989c35736c5d'	System	06 Apr 2021 21:04:30
User entered '06 Apr 2021 17:04:13'	System	06 Apr 2021 21:04:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-11T18:00:27-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '34040569-1176-492b-a7e7-6cf1f54bfd9e'	System	11 Apr 2021 22:02:22
User entered 'No (N)'	System	11 Apr 2021 22:02:22

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-11T18:00:41-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '34040569-1176-492b-a7e7-6cf1f54bfd9e'	System	11 Apr 2021 22:02:22
User entered 'No (N)'	System	11 Apr 2021 22:02:22

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-11T18:00:45-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '34040569-1176-492b-a7e7-6cf1f54bfd9e' User entered '11 Apr 2021 18:00:45'	System	11 Apr 2021 22:02:22
	System	11 Apr 2021 22:02:22

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-17T23:27:10-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2c4d7840-b59a-4c64-b5f2-8e421ff0e2c9'	System	18 Apr 2021 03:27:36
User entered 'No (N)'	System	18 Apr 2021 03:27:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-17T23:27:13-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2c4d7840-b59a-4c64-b5f2-8e421ff0e2c9'	System	18 Apr 2021 03:27:36
User entered 'No (N)'	System	18 Apr 2021 03:27:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-17T23:27:27-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '2c4d7840-b59a-4c64-b5f2-8e421ff0e2c9'	System	18 Apr 2021 03:27:36
User entered '17 Apr 2021 23:27:27'	System	18 Apr 2021 03:27:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-24T09:04:52-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'df405fe3-9573-45fe-91bd-de360bdc61ab'	System	24 Apr 2021 13:05:27
User entered 'No (N)'	System	24 Apr 2021 13:05:27

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-24T09:04:57-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'df405fe3-9573-45fe-91bd-de360bdc61ab'	System	24 Apr 2021 13:05:27
User entered 'No (N)'	System	24 Apr 2021 13:05:27

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-04-24T09:05:22-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: 'df405fe3-9573-45fe-91bd-de360bdc61ab'	System	24 Apr 2021 13:05:27
User entered '24 Apr 2021 09:05:22'	System	24 Apr 2021 13:05:27

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-05-01T12:32:15-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9dc492ba-967d-4091-a7bc-8b0dd50f5841'	System	01 May 2021 16:32:30
User entered 'No (N)'	System	01 May 2021 16:32:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-05-01T12:32:19-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9dc492ba-967d-4091-a7bc-8b0dd50f5841'	System	01 May 2021 16:32:30
User entered 'No (N)'	System	01 May 2021 16:32:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-05-01T12:32:23-04:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '9dc492ba-967d-4091-a7bc-8b0dd50f5841'	System	01 May 2021 16:32:30
User entered '01 May 2021 12:32:23'	System	01 May 2021 16:32:30

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:09:36

US3222611

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:36
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:09:36

US3222611

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:09:03

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-27T09:12:37-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '35bacb51-ac90-41fe-a2cf-202df3f8764d'	System	27 Feb 2021 14:12:56
User entered 'No (N)'	System	27 Feb 2021 14:12:56

US3222611

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:09:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:14:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a72d8d2be82b9e95)', Time: '2021-02-27T09:12:51-05:00', User OID: 'PatientReportedOutcome (US3222611)', ODM File OID: '35bacb51-ac90-41fe-a2cf-202df3f8764d' User entered '27 Feb 2021 09:12:51'	System	27 Feb 2021 14:12:56
	System	27 Feb 2021 14:12:56

US3222611

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	heather jackson (b) (4) (b) (4)	09 Dec 2020 13:44:41

US3222611

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '08 Dec 2020'	(b) (4) heather jackson (b) (4)	09 Dec 2020 13:44:41

US3222611

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	09 Dec 2020 13:44:41

US3222611

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered empty.	(b) (4) heather jackson (b) (4) (b) (4)	09 Dec 2020 13:44:41

US3222611

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 15:13:19

US3222611

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:18:08
User entered '1'	System	18 Jan 2021 15:13:19

US3222611

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 15:13:40

US3222611

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) [REDACTED]	23 Feb 2021 17:54:24
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6) [REDACTED]	18 Jan 2021 15:13:40

US3222611

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 15:13:40

US3222611

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 15:13:40

US3222611

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	18 Jan 2021 15:13:45

US3222611

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:47
User entered '1'	System	18 Jan 2021 15:13:45

US3222611

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:40:46

US3222611

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered '14 Feb 2021'	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:40:46

US3222611

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Contact Made (CONTACT MADE)'	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:40:46

US3222611

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:40:46

US3222611

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:31:10

US3222611

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:47
User entered 'I'	System	29 Mar 2021 14:31:10

US3222611

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:31:21

US3222611

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered '15 Mar 2021'	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:31:21

US3222611

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Contact Made (CONTACT MADE)'	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:31:21

US3222611

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:31:21

US3222611

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 15:40:47
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	29 Mar 2021 14:31:26

US3222611

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:47
User entered 'I'	System	29 Mar 2021 14:31:26

US3222611

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:31:49

US3222611

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered '13 Apr 2021'	Diana Toney (b) (4)	13 Apr 2021 14:31:49
	(b) (4)	

US3222611

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	13 Apr 2021 14:31:49
	(b) (4)	

US3222611

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 14:31:49

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	13 Apr 2021 14:31:57
	(b) (4)	

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	13 Apr 2021 14:31:57
	(b) (4)	

US3222611

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:31:57

US3222611

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered 'No (N)'	Diana Toney (b) (4)	13 Apr 2021 14:32:05
	(b) (4)	

US3222611

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:32:05

US3222611

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:32:23

US3222611

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered '13 Apr 2021'	Diana Toney (b) (4)	13 Apr 2021 14:32:23
	(b) (4)	

US3222611

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered '09:40'	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:32:23

US3222611

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 09:40'	System	13 Apr 2021 14:32:23

US3222611

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:32:29

US3222611

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 14:32:29

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:12:38

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:12:38

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:12:38

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'UNBLND_DECIDE'	System	15 Feb 2021 11:12:38

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:12:43

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:12:43

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '1'	System	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:09:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '1'	System	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered empty.	System	15 Feb 2021 11:14:59
DataPoint set to visible.	System	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered empty.	System	15 Feb 2021 11:14:59
DataPoint set to visible.	System	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
Signature has been broken.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:00:41
User entered '11:14' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 20:00:41
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '11:17'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '14 Feb 2021 11:14'	System	29 Mar 2021 20:00:41
User entered '14 Feb 2021 11:17'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '81'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'bpm'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'breaths/min'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '119'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mmHg'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '75'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mmHg'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered empty.	System	15 Feb 2021 11:14:59
DataPoint set to visible.	System	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '12:01'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '14 Feb 2021 12:01'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '37.2' C	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '78'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'bpm'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'breaths/min'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '131'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mmHg'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '76'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mmHg'	System	15 Feb 2021 11:14:59

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:15:09

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:15:09

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:15:25

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:15:25

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:15:25

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mRNA-1273'	System	15 Feb 2021 11:15:25
DataPoint set to visible.	System	15 Feb 2021 11:13:15

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:15:25

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '11:24'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:15:25

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '14 Feb 2021 11:24'	System	15 Feb 2021 11:15:25

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:15:25

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'ONCE'	System	15 Feb 2021 11:15:25

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 11:15:25

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:32

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:32

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '11:15'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:32

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '14 Feb 2021 11:15'	System	15 Feb 2021 11:13:32

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:42

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:42

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '11:18'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:42

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:03

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '14 Feb 2021 11:18'	System	15 Feb 2021 11:13:42

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:13:47

US3222611

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '1'	System	15 Feb 2021 11:13:47

US3222611

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:28:39

US3222611

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:28:39

US3222611

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:28:39

US3222611

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'spoke with subject/ no new meds/ no new illnesses/ no covid symptoms/ (b) (6)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:28:39

US3222611

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:28:45

US3222611

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '1'	System	22 Feb 2021 18:28:45

US3222611

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '1'	System	22 Feb 2021 18:28:45
DataPoint set to visible.	System	22 Feb 2021 18:28:45

US3222611

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:11:23

US3222611

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '15 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:11:23

US3222611

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	16 Mar 2021 22:11:23

US3222611

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'OLD29'	System	16 Mar 2021 22:11:23

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '15 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '11:00'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '15 Mar 2021 11:00'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '36.7' C	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Oral (Oral)'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '81'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'bpm'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '16'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'breaths/min'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '130'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mmHg'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '76'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mmHg'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Yes (Y)'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '15 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '12:40'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '15 Mar 2021 12:40'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '36.6' C	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Oral (Oral)'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '81'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'bpm'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '16'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'breaths/min'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '127'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mmHg'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '71'	Diana Toney (b) (4)	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mmHg'	System	16 Mar 2021 22:12:54

US3222611

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:13:10

US3222611

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '15 Mar 2021'	Diana Toney (b) (4)	16 Mar 2021 22:13:10

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:13:39

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:13:39

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered empty.	Diana Toney (b) (4)	16 Mar 2021 22:13:39

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'mRNA-1273'	System	16 Mar 2021 22:13:39
DataPoint set to visible.	System	22 Feb 2021 18:28:45

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '15 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:13:39

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '12:09'	(b) (4) Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:13:39

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered '15 Mar 2021 12:09'	System	16 Mar 2021 22:13:39

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Left Arm (LEFT ARM)'	Diana Toney (b) (4)	16 Mar 2021 22:13:39

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'ONCE'	System	16 Mar 2021 22:13:39

US3222611

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'INTRAMUSCULAR'	System	16 Mar 2021 22:13:39

US3222611

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Yes (Y)'	Diana Toney (b) (4)	16 Mar 2021 22:13:43

US3222611

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'I'	System	16 Mar 2021 22:13:43

US3222611

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:28:31

US3222611

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:28:31

US3222611

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:28:31

US3222611

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:28:31

US3222611

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:29:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:28:35

US3222611

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:39
User entered 'I'	System	22 Mar 2021 14:28:35

US3222611

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:32:55

US3222611

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered '13 Apr 2021'	Diana Toney (b) (4)	13 Apr 2021 14:32:55
	(b) (4)	

US3222611

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	13 Apr 2021 14:32:55
	(b) (4)	

US3222611

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	13 Apr 2021 14:32:55

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	13 Apr 2021 14:33:03
	(b) (4)	

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	13 Apr 2021 14:33:03
	(b) (4)	

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	13 Apr 2021 14:33:03
	(b) (4)	

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:33:03

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:16
User entered empty.	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:33:03

US3222611

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered 'No (N)'	Diana Toney (b) (4)	13 Apr 2021 14:33:08
	(b) (4)	

US3222611

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:16
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	13 Apr 2021 14:33:08
	(b) (4)	

US3222611

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	13 Apr 2021 14:33:22

US3222611

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
	(b) (4)	
User entered '13 Apr 2021'	Diana Toney (b) (4)	13 Apr 2021 14:33:22
	(b) (4)	

US3222611

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
	(b) (4)	
User entered '09:40'	Diana Toney (b) (4)	13 Apr 2021 14:33:22
	(b) (4)	

US3222611

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 09:40'	System	13 Apr 2021 14:33:22

US3222611

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:09:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:42:28
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:23:38
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	09 Oct 2020 14:43:58

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:41:57
User entered 'USA-US104-2020-mRNA-1273-P301000015'	System	02 Nov 2020 18:41:46
User entered 'New'	(b) (4), (b) (6)	02 Nov 2020 18:41:46

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Basal ganglia haemorrhage, LLT: Basal ganglia hemorrhage - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 17:59:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 17:59:50
Data point term sent to Coder	System	18 Nov 2020 17:44:43
User closed query 'CDM Coding, please split the term into two separate records, as 'MILD RIGHT UPPER AND RIGHT LOWER EXTREMITY WEAKNESS' and 'LEFT BASAL GANGLIA HEMORRHAGE' reporting each term separately with all relevant information e.g. start and stop dates etc.' (Site from System).	System	18 Nov 2020 17:44:40
Query 'CDM Coding, please split the term into two separate records, as 'MILD RIGHT UPPER AND RIGHT LOWER EXTREMITY WEAKNESS' and 'LEFT BASAL GANGLIA HEMORRHAGE' reporting each term separately with all relevant information e.g. start and stop dates etc.' answered with 'AE TERM HAS BEEN CORRECTED TO REFLECT ACTUAL AE NOTED IN SUBJECT CHART.' (Site from System).	Albert Garcia (b) (4)	18 Nov 2020 17:44:40
User entered 'LEFT BASAL GANGLIA HEMORRHAGE' reason for change: Data Entry Error	Albert Garcia (b) (4)	18 Nov 2020 17:44:15
User opened query 'CDM Coding, please split the term into two separate records, as 'MILD RIGHT UPPER AND RIGHT LOWER EXTREMITY WEAKNESS' and 'LEFT BASAL GANGLIA HEMORRHAGE' reporting each term separately with all relevant information e.g. start and stop dates etc.' (Site from System).	Coder Import (b) (4)	17 Nov 2020 03:48:52
Data point term sent to Coder	System	14 Nov 2020 16:49:26
DataPoint Un-verified.	douglas winter (b) (4)	14 Nov 2020 16:48:37
Coding entries removed.	douglas winter (b) (4)	14 Nov 2020 16:48:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'MILD RIGHT UPPER AND RIGHT LOWER EXTREMITY WEAKNESS WITH LEFT BASAL GANGLIA HEMORRHAGE' reason for change: Data Entry Error DataPoint Verified.	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:48:37
	(b) (4), (b) (6)	05 Nov 2020 19:43:16
User coded data point as SOC: Nervous system disorders, HLG: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Basal ganglia haemorrhage, LLT: Basal ganglia hemorrhage - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 10:59:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 10:59:15
Data point term sent to Coder	System	30 Oct 2020 18:50:51
User entered 'LEFT BASAL GANGLIA HEMORRHAGE'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:18:03
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'NOT A COVID EVENT' (Site from Safety).	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:41:28
DataPoint Un-verified.	Jennifer Dittman (b) (4) (b) (4)	11 Nov 2020 12:59:28
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	11 Nov 2020 12:59:28
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:43:16
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 20:08:12
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '29 Oct 2020'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
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	30 Oct 2020 18:51:28
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:51:28
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	30 Oct 2020 18:50:06
User entered '18:40'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:51:28
User entered '29 Oct 2020 18:40'	System	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Nov 2020 15:04:59
DataPoint Un-verified.	douglas winter (b) (4)	14 Nov 2020 15:04:59
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 15:04:59
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Nov 2020 15:03:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'Yes (Y)'	douglas winter (b) (4)	30 Oct 2020 18:50:06
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:04:59
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)	16 Nov 2020 14:03:56
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'UPDATED' (Site from System).	douglas winter (b) (4) (b) (4)	14 Nov 2020 15:04:47
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 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	14 Nov 2020 15:04:16
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Nov 2020 15:03:54
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	14 Nov 2020 15:03:54
User entered '10 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 15:03:54
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)	09 Nov 2020 20:19:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	12 Nov 2020 18:42:34
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	12 Nov 2020 18:42:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:43:16
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Oct 2020 18:50:06
User entered '1'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '29 Oct 2020'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered '10 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 15:05:45
	(b) (4)	
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:18:12
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4)	12 Nov 2020 18:43:00
	(b) (4)	
DataPoint Un-verified.	douglas winter (b) (4)	12 Nov 2020 18:42:34
	(b) (4)	
User entered '11 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4)	12 Nov 2020 18:42:34
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:18:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:43:16
	(b) (4)	
User entered empty.	douglas winter (b) (4)	30 Oct 2020 18:50:06
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	14 Nov 2020 16:47:00
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	14 Nov 2020 16:47:00
DataPoint Un-verified.	douglas winter (b) (4)	14 Nov 2020 16:47:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Nov 2020 16:47:00
DataPoint Verified.	douglas winter (b) (4)	14 Nov 2020 16:47:00
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'Unknown (UNK)'	System	30 Oct 2020 18:50:06
	douglas winter (b) (4)	30 Oct 2020 18:50:06
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

US3222611

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 09:37:40
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:36:03
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:35:58
User entered '0' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:35:58
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:52:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '1'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:35:58
User entered '1' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:35:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 15:04:59
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:19:06
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:43:51
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:43:23
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:43:23
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:19:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered 'Unknown (UNKNOWN)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:43:16
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per DM CLR: SAE Narrative = MRA HEAD. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 14:11:25
User closed query 'Per CDM: Per previous query response "updated"; however, the update is not obvious please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:11:11
User closed query 'Per DM CLR - RQ: Sites response "UPDATED" noted. However, SAE Narrative = LABS (COAGULATION) PT (9.0 - 11.6 SEC) 10.4 INR (2.0 - 3.0) 1.0 L PTT (SP) (24.0 - 32.0 SEC) 27.1 were still not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 10:15:04
Query 'Per CDM: Per previous query response "updated"; however, the update is not obvious please provide location of update such as log line number. Thank you.' answered with 'mra added to con procedures' (Site from DM).	gail lavine (b) (4) (b) (4)	20 Jan 2021 13:58:18
Query 'Per DM CLR: SAE Narrative = MRA HEAD. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'MRA added to con procedures' (Site from DM).	gail lavine (b) (4) (b) (4)	20 Jan 2021 13:57:27
Query 'Per DM CLR - RQ: Sites response "UPDATED" noted. However, SAE Narrative = LABS (COAGULATION) PT (9.0 - 11.6 SEC) 10.4 INR (2.0 - 3.0) 1.0 L PTT (SP) (24.0 - 32.0 SEC) 27.1 were still not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'labs added to con procedures' (Site from DM).	gail lavine (b) (4) (b) (4)	20 Jan 2021 12:38:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR - RQ: Sites response "UPDATED" noted. However, SAE Narrative = LABS (COAGULATION) PT (9.0 - 11.6 SEC) 10.4 INR (2.0 - 3.0) 1.0 L PTT (SP) (24.0 - 32.0 SEC) 27.1 were still not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 02:10:14
User opened query 'Per DM CLR: SAE Narrative = MRA HEAD. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 02:09:34
User opened query 'Per CDM: Per previous query response "updated"; however, the update is not obvious please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:36:17
User closed query 'Per DM CLR: SAE Narrative = LABS (COAGULATION). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:36:17
User closed query 'Per DM CLR: SAE Narrative = 29/OCT/2020 ECG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:34:47
User closed query 'Per DM CLR: SAE Narrative = MRI HEAD WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:34:43
User closed query 'Per DM CLR: SAE Narrative = A RIGHT LOWER EXTREMITY SONOGRAM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:33:03
User closed query 'Per DM CLR: SAE Narrative = COLOR AND SPECTRAL DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:32:10

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = CAT SCAN CT STROKE ALERT 10/29/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:31:39
Query 'Per DM CLR: SAE Narrative = LABS (COAGULATION). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	18 Dec 2020 16:40:45
Query 'Per DM CLR: SAE Narrative = 29/OCT/2020 ECG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	18 Dec 2020 16:40:41
Query 'Per DM CLR: SAE Narrative = MRI HEAD WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	18 Dec 2020 16:40:38
Query 'Per DM CLR: SAE Narrative = A RIGHT LOWER EXTREMITY SONOGRAM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	18 Dec 2020 16:40:33
Query 'Per DM CLR: SAE Narrative = COLOR AND SPECTRAL DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	18 Dec 2020 16:40:29
Query 'Per DM CLR: SAE Narrative = CAT SCAN CT STROKE ALERT 10/29/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	18 Dec 2020 16:40:25
User opened query 'Per DM CLR: SAE Narrative = LABS (COAGULATION). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:52:18

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = 29/OCT/2020 ECG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:52:12
User opened query 'Per DM CLR: SAE Narrative = MRI HEAD WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:52:06
User opened query 'Per DM CLR: SAE Narrative = A RIGHT LOWER EXTREMITY SONOGRAM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:51:59
User opened query 'Per DM CLR: SAE Narrative = COLOR AND SPECTRAL DOPPLER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:51:53
User opened query 'Per DM CLR: SAE Narrative = CAT SCAN CT STROKE ALERT 10/29/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:51:46
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:04:05
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:04:02
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'EMERGENCY RECORDS, DISCHARGE SUMMARY EMAIL TODAY.' (Site from Safety).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:32:39

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:49:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADMISSION 29/OCT/2020 DISCHARGE 10/NOV/2020 55 YO MALE DW P/W NUMBNESS THE PATIENT PRESENTED WITH RIGHT ARM AND RIGHT LEG NUMBNESS AND WEAKNESS, RIGHT HEMIPARESIS. 29/OCT/2020 @ ONSET 10:20 AM WHILE AT WORK. DENIES WEAKNESS. EMS REPORTED PATIENT VERY ATAXIC, LEANING TO THE RIGHT WHEN TRYING TO AMBULATE, ALMOST FELL. PATIENT DENIES HX OF HTN, NO ANTICOAGULATION. NO FAMILY HX OF STROKES OR ANEURYSMS. BP 184/98 ON EMS ARRIVAL. SENSATION (ARMS/LEGS/FACE) COMPLETE SENSORY LOSS DIAGNOSTICS 1. CAT SCAN – CT STROKE ALERT 10/29/2020 TIME 12:18 PM. FINDINGS: LEFT BASAL GANGLIA HEMORRHAGE MEASURING 3.2 X 1.6 CM WITH MILD SURROUNDING EDEMA. 2. COLOR AND SPECTRAL DOPPLER EVAL OF THE ARTERIAL VASCULATURE IN BOTH LOWER EXTREMITIES. FINDINGS: NO ARTERIAL OCCLUSION. NO EVIDENCE OF ELEVATED VELOCITIES TO SUGGEST FOCAL STENOSIS. 3. A RIGHT LOWER EXTREMITY SONOGRAM OF THE DEEP VENOUS SYSTEM OF THE LOWER EXTREMITY WAS PERFORMED ASSESSING GRAY SCALE APPEARANCE, COLOR, DOPPLER FLOW, AUGMENTATION AND COMPRESSIBILITY. FINDINGS: NO EVIDENCE OF DVT IN THE RIGHT LOWER EXTREMITY. 4. MRA HEAD WAS PERFORMED. 2D TIME OF FLIGHT TECHNIQUE WAS UTIIZED. 3D REFORMATTED IMAGES ALSO OBTAINED. FINDINGS: NORMAL MRA OF THE HEAD 5. MRI OF THE BRAIN. AXIAL, SAGITTAL, AND CORONAL IMAGES WERE OBTAINED USING T1, T2, T2 FLAIR AND DIFFUSION	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:24:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
WEIGHTED SEQUENCES. FINDINGS: EXTENSIVE PERIVENTRICULAR CHRONIC MICROVASCULAR ISCHEMIC CHANGES ARE NOTED. LEFT BASAL GANGLIA HEMORRHAGE WITH SURROUNDING EDEMA UNCHANGED WHEN COMPARED TO THE PRIOR STUDY. 29/OCT/2020 ECG NORMAL VITALS PULSE OX 98%
B/P 143/73 B/P MEAN 96 O2 DELIVERY ROOM AIR PULSE 92
RESP 18 TEMP 36.9
MEDICATIONS FAMOTIDINE 20 MG BID PO NICARDIPINE HCL 50 MG TITRATE IV DEXTROSE 250 ML NICARDIPINE HCL 50 MG X1FED ONE IV DEXTROSE 250 ML. LABS (COAGULATION) PT (9.0 - 11.6 SEC) 10.4 INR (2.0 - 3.0) 1.0 L PTT (SP) (24.0 - 32.0 SEC) 27.1' reason for change: Data Entry Error DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:50:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Narrative](#)

Audit	User	Time (GMT)
User entered 'I WAS TOLD AT NOON TODAY WHEN DR. (b) (6) CAME IN THAT THIS PATIENT WAS ADMITTED TO CENTRAL FLORIDA REGIONAL HOSPITAL FOR A CVA. THIS IS HIS PATIENT AND DR. (b) (6) HANDED ME MEDICAL RECORDS. THE PATIENT PRESENTED WITH RIGHT ARM AND RIGHT LEG NUMBNESS AND WEAKNESS, RIGHT HEMIPARESIS. VITALS PULSE OX 98% B/P 143/73 B/P MEAN 96 O2 DELIVERY ROOM AIR PULSE 92 RESP 18 TEMP 36.9 MEDICATIONS FAMOTIDINE 20 MG BID PO NICARDIPINE HCL 50 MG TITRATE IV DEXTROSE 250 ML NICARDIPINE HCL 50 MG X1FED ONE IV DEXTROSE 250 ML. LABS (COAGULATION) PT (9.0 - 11.6 SEC) 10.4 INR (2.0 - 3.0) 1.0 L PTT (SP) (24.0 - 32.0 SEC) 27.1 CAT SCAN IMPRESSION LEFT BASAL GANGLIA HEMORRHAGE MEASURING 3.2 X 1.6 CM WITH MILD SURROUNDING EDEMA. I SPOKE WITH THE PATIENT TODAY 12/NOV/2020. HE WAS DISCHARGED YESTERDAY 11/NOV/2020, HE HAS NO FEELINGS TO HIS FEET OR RIGHT SIDE OF BODY. HIS WIFE WILL FAX ME HIS DISCHARGE RECORDS. RECORDS WILL BE REQUESTED.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	12 Nov 2020 18:50:00
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:20:39
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:20:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:43:16

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'I WAS TOLD AT NOON TODAY WHEN DR. (b) (6) CAME IN THAT THIS PATIENT WAS ADMITTED TO CENTRAL FLORIDA REGIONAL HOSPITAL FOR A CVA. THIS IS HIS PATIENT AND DR. (b) (6) HANDED ME MEDICAL RECORDS. THE PATIENT PRESENTED WITH RIGHT ARM AND RIGHT LEG NUMBNESS AND WEAKNESS, RIGHT HEMIPARESIS. VITALS PULSE OX 98% B/P 143/73 B/P MEAN 96 O2 DELIVERY ROOM AIR PULSE 92 RESP 18 TEMP 36.9 MEDICATIONS FAMOTIDINE 20 MG BID PO NICARDIPINE HCL 50 MG TITRATE IV DEXTROSE 250 ML NICARDIPINE HCL 50 MG X1FED ONE IV DEXTROSE 250 ML. LABS (COAGULATION) PT (9.0 - 11.6 SEC) 10.4 INR (2.0 - 3.0) 1.0 L PTT (SP) (24.0 - 32.0 SEC) 27.1 CAT SCAN IMPRESSION LEFT BASAL GANGLIA HEMORRHAGE MEASURING 3.2 X 1.6 CM WITH MILD SURROUNDING EDEMA. RECORDS WILL BE REQUESTED.'	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 18:50:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Nov 2020 17:22:52
Data point term sent to Coder	(b) (4)	
User entered 'HYPERTENSION'	System	14 Nov 2020 17:21:36
	douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:21:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 17:21:30
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 17:21:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:21:19
User entered empty.	System	14 Nov 2020 17:21:19
	douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '29 Oct 2020'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User entered empty.	System	14 Nov 2020 17:21:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:57:15
Query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' answered with 'UPDATED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 18:35:52
User entered 'No (N)' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 18:35:40
User opened query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:17:02
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:21:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 18:35:40
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	Alicia Cevera (b) (4)	19 Nov 2020 18:35:40
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'UPDATED' (Site from System).	(b) (4)	17 Nov 2020 16:08:27
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	douglas winter (b) (4)	14 Nov 2020 17:26:47
User entered empty.	(b) (4)	14 Nov 2020 17:21:19
	douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User entered empty.	System	14 Nov 2020 17:21:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '1'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	(b) (4)	
reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 17:27:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	
	douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'ALTHOUGH NOW TREATED WITH MEDICATION WILL CONTINUE WITH DIAGNOSIS' reason for change: Data Entry Error	(b) (4) Alicia Cevera (b) (4)	19 Nov 2020 18:35:40
User entered 'NO BILATERAL FEET CONTROL, RIGHT SIDE OF BODY PARALYSIS.' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 17:27:10
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:21:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'THIS NEW DIAGNOSIS IS SECONDARY TO THE SAE.' reason for change:	(b) (4)	
Data Entry Error	douglas winter (b) (4)	14 Nov 2020 17:27:10
User entered 'THIS WAS SECONDARY TO THE SAE.'	(b) (4)	
	douglas winter (b) (4)	14 Nov 2020 17:21:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User entered '0'	System	14 Nov 2020 17:21:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33
User entered '1'	System	14 Nov 2020 17:21:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Gait disturbances, PT: Gait disturbance, LLT: Gait disturbance - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 03:51:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 03:51:57
Data point term sent to Coder	System	14 Nov 2020 17:30:38
User entered 'GAIT DYSFUNCTION AND ADL'S AND SELF-CARE DEFICITS'	douglas winter (b) (4)	14 Nov 2020 17:30:28

US3222611

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:30:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 17:30:39
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 17:30:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:30:28
User entered empty.	System	14 Nov 2020 17:30:28
	douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '29 Oct 2020'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User entered empty.	System	14 Nov 2020 17:30:28

US3222611

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:06:31
Query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' answered with 'UPDATED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 18:33:32
User entered 'No (N)' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 18:33:25
User opened query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:18:56
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Alicia Cevera (b) (4)	19 Nov 2020 18:33:25
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:18:46
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'UPDATED' (Site from System).	douglas winter (b) (4)	14 Nov 2020 17:30:47
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).		14 Nov 2020 17:30:28
User entered empty.	douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User entered empty.	System	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 09:39:22
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:41:19
User entered '0' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:41:12
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 12:49:48
User entered '1'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered '1' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:41:12
User entered '0'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'NO BILATERAL FEET CONTROL, RIGHT SIDE OF BODY PARALYSIS.'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'THIS DIAGNOSIS IS SECONDARY TO THE SAE'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User entered '0'	System	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35
User entered '1'	System	14 Nov 2020 17:30:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERCHOLESTEROLEMIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 09:43:18
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERCHOLESTEROLEMIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'CANNOT BE CONFIRMED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:42:21
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERCHOLESTEROLEMIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:49:14
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Dyslipidaemia, LLT: Dyslipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 17:33:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 17:33:51
Data point term sent to Coder	System	14 Nov 2020 17:32:39
User entered 'DYSLIPIDEMIA'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:32:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 17:32:39
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 17:32:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:32:17
User entered empty.	System	14 Nov 2020 17:32:17
	douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '29 Oct 2020'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User entered empty.	System	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:07:03
Query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' answered with 'UPDATED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 18:25:45
User entered 'No (N)' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 18:25:32
User opened query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:19:25
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	(b) (4)	19 Nov 2020 18:26:02
User entered '15 Nov 2020' reason for change: Data Entry Error	System	19 Nov 2020 18:26:02
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	Alicia Cevera (b) (4)	19 Nov 2020 18:26:02
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	19 Nov 2020 18:25:32
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'UPDATED' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:19:18
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	douglas winter (b) (4)	14 Nov 2020 17:32:45
User entered empty.	(b) (4)	14 Nov 2020 17:32:17
	douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User entered empty.	System	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per DM CLR - RQ: Site's response noted. However, please update the CM indication to include this AE so there will be an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 14:28:11
Query 'Per DM CLR - RQ: Site's response noted. However, please update the CM indication to include this AE so there will be an appropriate match. ' answered with 'updated Rosuvastatin w dyslipidemia' (Site from DM).	gail lavine (b) (4) (b) (4)	20 Jan 2021 13:48:18
User opened query 'Per DM CLR - RQ: Site's response noted. However, please update the CM indication to include this AE so there will be an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 02:11:45
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:46:10
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'SUBJECT IS ALREADY ON A MEDICATION FOR HYPERCHOLESTEROLEMIA WHICH WOULD BE USED TO TREAT THIS CONDISTION AS WELL. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:42:56
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:49:28
User entered 'I'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'THIS HAS BEEN TREATED WITH MEDICATION HOWEVER WILL NEVER RESOLVE WITHOUT MEDICATION.' reason for change: Data Entry Error	Alicia Cevera (b) (4)	19 Nov 2020 18:27:31
User entered 'NO BILATERAL FEET CONTROL, RIGHT SIDE OF BODY PARALYSIS.'	douglas winter (b) (4)	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'THIS DIAGNOSIS IS SECONDARY TO THE SAE.'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User entered '0'	System	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37
User entered '1'	System	14 Nov 2020 17:32:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Cortical dysfunction NEC, PT: Aphasia, LLT: Expressive and receptive aphasia - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 17:34:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 17:34:35
Data point term sent to Coder	System	18 Dec 2020 16:45:30
Coding entries removed.	Albert Garcia (b) (4)	18 Dec 2020 16:44:54
User entered 'MILD EXPRESSIVE AND RECEPTIVE APHASIA.' reason for change: Data Entry Error	Albert Garcia (b) (4)	18 Dec 2020 16:44:54
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Cortical dysfunction NEC, PT: Aphasia, LLT: Expressive and receptive aphasia - version MedDRA\23.0.	Coder Import (b) (4)	14 Nov 2020 19:02:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Nov 2020 19:02:51
Data point term sent to Coder	System	14 Nov 2020 17:34:40
User entered 'MILD EXPRESSIVE AND RECEPTIVE AND RECEPTIVE APHASIA.'	douglas winter (b) (4)	14 Nov 2020 17:34:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '29 Oct 2020'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User entered empty.	System	14 Nov 2020 17:34:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:08:11
Query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' answered with 'UPDATED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 18:29:57
User entered 'No (N)' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 18:28:54
User opened query 'Per CDM: Outcome is 'Recovered/Resolved with Sequelae' however, event is recorded as 'Ongoing'? Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:20:15
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:34:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	19 Nov 2020 18:29:48
User entered '10 Nov 2020' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	19 Nov 2020 18:29:48
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	19 Nov 2020 18:28:54
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 16:20:05
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'UPDATED' (Site from System).	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:34:38
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Nov 2020 17:34:31
User entered empty.	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:34:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User entered empty.	System	14 Nov 2020 17:34:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:34:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 17:34:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 17:34:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:34:31
User entered empty.	System	14 Nov 2020 17:34:31
	douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 17:34:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 17:34:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Nov 2020 17:34:31
	douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:34:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 17:34:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	douglas winter (b) (4)	14 Nov 2020 17:34:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Nov 2020 17:34:31
User entered empty.	System	14 Nov 2020 17:34:31
	douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 09:46:54
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:45:20
User entered '0' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:45:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:50:02
User entered '1'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:34:31

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered '1' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:45:16
User entered '0'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:34:31

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:34:31

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'RESIDUAL EFFECTS FROM CVA' reason for change: Data Entry Error	(b) (4) Alicia Cevera (b) (4)	19 Nov 2020 18:31:36
User entered 'NO BILATERAL FEET CONTROL, RIGHT SIDE OF BODY PARALYSIS.'	douglas winter (b) (4) (b) (4)	14 Nov 2020 17:34:31

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'THIS DIAGNOSIS IS SECONDARY TO THE SAE.'	(b) (4) douglas winter (b) (4)	14 Nov 2020 17:34:31

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User entered '0'	System	14 Nov 2020 17:34:31

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42
User entered '1'	System	14 Nov 2020 17:34:31

US3222611

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:08:42

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Neuralgia, LLT: Nerve pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Apr 2021 13:50:44
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 13:50:44
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Post-traumatic pain, LLT: Post-traumatic pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:01:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:01:56
Data point term sent to Coder	System	09 Apr 2021 17:59:32
User entered 'NERVE PAIN SECONDARY TO STROKE'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
	(b) (4)	
User entered '12 Jan 2021'	Crystal Paccione (b) (4)	09 Apr 2021 17:59:15
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Crystal Paccione (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '0'	(b) (4) Crystal Paccione (b) (4)	09 Apr 2021 17:59:15
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered '0'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
	(b) (4)	
User entered '0'	Crystal Paccione (b) (4)	09 Apr 2021 17:59:15
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered '0'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered '0'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered '0'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Crystal Paccione (b) (4)	09 Apr 2021 17:59:15
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'Not Applicable (NOT APPLICABLE)'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'None (NONE)'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
	(b) (4)	
User entered '0'	Crystal Paccione (b) (4)	09 Apr 2021 17:59:15
	(b) (4)	

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered '1'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered '0'	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Crystal Paccione (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 17:59:15

US3222611

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:09:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 17:59:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:09:03

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User closed query 'Per ETRTR: According to SAE "Left Basal Ganglia Hemorrhage " page, medication was dosed. Please add Medication dosing details for SAE "Left Basal Ganglia Hemorrhage " within ConMeds page, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 20:53:26
Query 'Per ETRTR: According to SAE "Left Basal Ganglia Hemorrhage " page, medication was dosed. Please add Medication dosing details for SAE "Left Basal Ganglia Hemorrhage " within ConMeds page, thanks.' answered with 'UPDATED DATA' (Site from CRA).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:37:31
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:48
User opened query 'Per ETRTR: According to SAE "Left Basal Ganglia Hemorrhage " page, medication was dosed. Please add Medication dosing details for SAE "Left Basal Ganglia Hemorrhage " within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 00:52:17
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:42:09

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:49:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:49:54
Data point term sent to Coder User entered 'AMBIEN'	System Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:31 21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:22:44
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' answered with 'CORRECTED' (Site from DM).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:34:10
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:33:59
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:33:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:54:16
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'INSOMNIA'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '5'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'as needed (PRN)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per CDM: Please verify if this pertains to (#4) INSOMNIA (start date UNK-2019) in the Medical History eCRF? If yes, note that Con Med start date is prior to the start date of the Med History condition Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 10:34:00
Query 'Per CDM: Please verify if this pertains to (#4) INSOMNIA (start date UNK-2019) in the Medical History eCRF? If yes, note that Con Med start date is prior to the start date of the Med History condition Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Dec 2020 14:09:54
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	04 Dec 2020 14:09:49
User entered 'UN UNK 2019' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	04 Dec 2020 14:09:49
User opened query 'Per CDM: Please verify if this pertains to (#4) INSOMNIA (start date UNK-2019) in the Medical History eCRF? If yes, note that Con Med start date is prior to the start date of the Med History condition Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 23:24:14
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'UN UNK 2014'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:47:38

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	14 Nov 2020 18:35:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Nov 2020 18:35:51
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	14 Nov 2020 18:35:16 14 Nov 2020 18:34:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 05:35:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 05:35:50
Data point term sent to Coder User entered 'METFORMIN'	System Albert Garcia (b) (4)	21 Sep 2020 18:48:32 21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:25:01
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' answered with 'CORRECTED' (Site from DM).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:35:17
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:35:10
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:35:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:54:29
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:34:41
User entered 'DIABETES TYPE II' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:34:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	05 Nov 2020 20:04:55
User entered 'DIABE500TES TYPE II'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '500'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'twice daily (BID)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'UN UNK 2014'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 18:48:23

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Dec 2020 14:10:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Dec 2020 14:10:54
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	04 Dec 2020 14:10:14 04 Dec 2020 14:10:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 18:50:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Sep 2020 18:50:56
Data point term sent to Coder	System	21 Sep 2020 18:49:35
User entered 'OMEPROZOLE'	Albert Garcia (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:25:26
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' answered with 'CORRECTED' (Site from DM).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:35:44
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:35:34
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:35:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:54:41
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per CDM: Please verify if this pertains to #3 GERD (UNK-2014) in the Medical History eCRF? If yes, note that Con Med 'indication' does not match the corresponding MH record. Please review and reconcile Con Med and MH as appropriate else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 10:34:51
Query 'Per CDM: Please verify if this pertains to #3 GERD (UNK-2014) in the Medical History eCRF? If yes, note that Con Med 'indication' does not match the corresponding MH record. Please review and reconcile Con Med and MH as appropriate else clarify.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Dec 2020 14:10:14
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	04 Dec 2020 14:10:10
User entered 'GERD' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	04 Dec 2020 14:10:10
User opened query 'Per CDM: Please verify if this pertains to #3 GERD (UNK-2014) in the Medical History eCRF? If yes, note that Con Med 'indication' does not match the corresponding MH record. Please review and reconcile Con Med and MH as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 23:27:19
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'ACID REFLUX'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '20'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'UN UNK 2014'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 18:49:20

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Jan 2021 14:03:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:03:05
Data point term sent to Coder Coding entries removed.	System gail lavine (b) (4) (b) (4)	20 Jan 2021 13:48:12 20 Jan 2021 13:47:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:51:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:51:51
Data point term sent to Coder User entered 'ROSUVASTATIN'	System Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:36 21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:27:46
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' answered with 'CORRECTED' (Site from DM).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:36:07
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:35:59
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:35:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:54:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Un-verified.	(b) (4)	
	gail lavine (b) (4)	20 Jan 2021 13:47:45
	(b) (4)	
User entered 'HYPERCHOLESTEROLEMIA/ dyslipidemia' reason for change: Data Entry Error	gail lavine (b) (4)	20 Jan 2021 13:47:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'HYPERCHOLESTEROLEMIA'	Albert Garcia (b) (4)	21 Sep 2020 18:50:05
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '40'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'UN UNK 2014'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 18:50:05

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:52:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:52:55
Data point term sent to Coder	System	21 Sep 2020 18:51:41
User entered 'TRULICITY'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:28:10
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' answered with 'CORRECTED' (Site from DM).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:36:32
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:36:23
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:36:23
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:55:17
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'DIABETESTYPE II'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '1.5'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'every week (QS)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Subcutaneous (SUBCUTANEOUS)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'UN UNK 2014'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	21 Sep 2020 18:50:56

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE;METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: XIGDUO - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 11:41:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 11:41:21
Data point term sent to Coder Coding entries removed.	System Alicia Cevera (b) (4)	10 Oct 2020 11:41:07 10 Oct 2020 11:40:25
User entered 'XIGDUO' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	10 Oct 2020 11:40:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE;METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: XIGDUO - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 06:13:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 06:13:01
Data point term sent to Coder	System	21 Sep 2020 18:52:43
User entered 'ZIGDUO'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:28:31
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' answered with 'CORRECTED' (Site from DM).	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:37:05
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:36:58
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 18:36:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:04:55
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:55:30
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'DIABETES TYPE II'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '5/500'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'UN UNK 2014'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered '0'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered empty.	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:04:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 18:52:03

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NICARDIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 19:05:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 19:05:51
Data point term sent to Coder	System	14 Nov 2020 16:34:18
User entered 'NICARDIPINE'	douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'HYPERTENSION'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '50'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '29 Oct 2020'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '29 Oct 2020'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:33:22
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User entered empty.	System	14 Nov 2020 16:33:22

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User entered empty.	System	14 Nov 2020 16:33:22

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:22
User entered empty.	System	14 Nov 2020 16:33:22

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 07:19:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 07:19:47
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	08 Dec 2020 20:20:51 08 Dec 2020 20:20:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Nov 2020 18:50:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Nov 2020 18:50:52
Data point term sent to Coder User entered 'DEXTROSE'	System douglas winter (b) (4)	14 Nov 2020 16:35:20 14 Nov 2020 16:34:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 08:25:24
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'corrected' (Site from DM).	Crystal Paccione (b) (4)	09 Apr 2021 17:50:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 17:50:50
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 01:23:01
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:34:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 12:40:00
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	08 Dec 2020 20:20:43
User entered 'DIABETES TYPE II' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	08 Dec 2020 20:20:39
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:20:38
User entered 'PREVENTATIVE'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:34:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '250'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'mL (mL)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '29 Oct 2020'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '0'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '30 Oct 2020'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	14 Nov 2020 16:34:47
	(b) (4)	

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User entered empty.	System	14 Nov 2020 16:34:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User entered empty.	System	14 Nov 2020 16:34:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:16:54
User entered empty.	System	14 Nov 2020 16:34:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 12:41:03
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification.' answered with 'CONDITION DID NOT WORSEN. MEDICATION WAS ADDED TO BETTER CONTROL CONDITION. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	08 Dec 2020 20:19:13
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:22:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:45:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:45:51
Data point term sent to Coder	System	14 Nov 2020 16:45:24
User entered 'FAMOTIDINE'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:35:58
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	08 Dec 2020 20:19:21
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	08 Dec 2020 20:18:41
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:22:35
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'GERD' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:45:06
User entered 'PREVENTATIVE'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered '20'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '29 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered '0'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered empty.	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Nov 2020 16:44:46

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	20 Jan 2021 14:03:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 14:03:05
Data point term sent to Coder Coding entries removed.	System gail lavine (b) (4) (b) (4)	20 Jan 2021 12:17:55 20 Jan 2021 12:17:26
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) (b) (4)	20 Jan 2021 08:28:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 08:28:06
Data point term sent to Coder User entered 'tramadol'	System (b) (4), (b) (6)	19 Jan 2021 15:29:31 19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 15:32:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Please note that there is no AE that matches the indication of Con Med #s 10, 11, 12 and 13 during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:24:03
Query 'Per DM CLR: Please note that there is no AE that matches the indication of Con Med #s 10, 11, 12 and 13 during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'A/E added' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 17:57:44
User opened query 'Per DM CLR: Please note that there is no AE that matches the indication of Con Med #s 10, 11, 12 and 13 during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:21:12
User entered 'NERVE PAIN secondary to stroke' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	20 Jan 2021 12:17:26
User entered 'nerve pain from stroke he recently had'	(b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '50'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Jan 2021 15:29:17

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Jan 2021 23:23:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 23:23:12
Data point term sent to Coder	System	19 Jan 2021 15:31:33
User entered 'gabapentin'	(b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 15:32:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 15:32:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 15:32:07
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 15:31:28
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'NERVE PAIN FROM STROKE HE RECENTLY HAD'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '300'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Jan 2021 15:31:28

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Jan 2021 22:33:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 22:33:10
Data point term sent to Coder	System	19 Jan 2021 15:41:40
User entered 'baclofen'	(b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'NERVE PAIN FROM STROKE HE RECENTLY HAD'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '10'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Jan 2021 15:41:15

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Jan 2021 22:24:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 22:24:10
Data point term sent to Coder	System	19 Jan 2021 15:46:43
User entered 'amitriptyline'	(b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'NERVE PAIN FROM STROKE HE RECENTLY HAD'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '10'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:09:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Jan 2021 15:45:47

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:09:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:38:28
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	09 Oct 2020 14:43:51

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:09:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered '29 Oct 2020'	Albert Garcia (b) (4)	18 Dec 2020 16:38:58
	(b) (4)	

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:09:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Please specify the location of CT SCAN (e.g. CT SCAN ON ABDOMEN, CT SCAN ON CHEST, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 10:04:20
Query 'Per DM CLR: Please specify the location of CT SCAN (e.g. CT SCAN ON ABDOMEN, CT SCAN ON CHEST, etc.). Update Concomitant Procedure eCRF as appropriate. ' answered with 'added location per records' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 18:05:49
Signature has been broken.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 18:05:32
User entered 'CT SCAN of the brain' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 18:05:32
User opened query 'Per DM CLR: Please specify the location of CT SCAN (e.g. CT SCAN ON ABDOMEN, CT SCAN ON CHEST, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:33:57
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'CT SCAN'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:38:58

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered 'Adverse Event (AE)'	Albert Garcia (b) (4)	18 Dec 2020 16:38:58
	(b) (4)	

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:09:03

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:38:58

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:09:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:20
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '29 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:17

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:09:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'COLOR/SPECTRAL DOPPLER'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:17

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Adverse Event (AE)'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:17

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:09:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:17

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:09:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:25
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '29 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:39

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:09:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'SONOGRAM - LOWER RIGHT EXTREMITIES'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:39

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Adverse Event (AE)'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:39

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:09:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:39

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:09:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:29
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	gail lavine (b) (4)	20 Jan 2021 12:32:19
User entered '29 Oct 2020'	(b) (4)	
	Albert Garcia (b) (4)	18 Dec 2020 16:39:52
	(b) (4)	

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:09:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:08:13
User closed query 'Per DM CLR: Please specify the location of MRI (e.g. BRAIN MRI, CHEST MRI, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 10:04:32
Query 'Per DM CLR: Please specify the location of MRI (e.g. BRAIN MRI, CHEST MRI, etc.). Update Concomitant Procedure eCRF as appropriate. ' answered with 'location added per query' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 18:07:58
Signature has been broken.	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 18:07:46
User entered 'MRI head and neck' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	09 Apr 2021 18:07:46
User opened query 'Per DM CLR: Please specify the location of MRI (e.g. BRAIN MRI, CHEST MRI, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:34:29
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'MRI'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:52

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:29
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Adverse Event (AE)'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:52

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:09:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:29
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:39:52

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:09:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:33
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered '29 Oct 2020'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:40:04

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:09:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:33
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'ECG'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:40:04

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:33
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered 'Adverse Event (AE)'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:40:04

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:09:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:33
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	23 Feb 2021 17:54:24
User entered empty.	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 16:40:04

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:09:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '31 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	20 Jan 2021 12:37:10

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:09:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'chemistry, PT, PTT, and complete blood count'	(b) (4) gail lavine (b) (4) (b) (4)	20 Jan 2021 12:37:10

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	20 Jan 2021 12:37:10

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:09:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:36
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	20 Jan 2021 12:37:10

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:09:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:41
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '31 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	20 Jan 2021 13:56:50

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:09:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:41
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'MRA'	(b) (4) gail lavine (b) (4) (b) (4)	20 Jan 2021 13:56:50

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:09:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:41
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	20 Jan 2021 13:56:50

US3222611

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:09:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:41
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	20 Jan 2021 13:56:50

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'USA-US104-2020-MRNA-1273-P301000015'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Teresa'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Tracy'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Becker'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Kowalski'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '6550 Mapleridge Street'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Houston'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '77081'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:19:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
User entered 'US'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered '5'	System	21 Dec 2020 15:59:47
User entered '4'	System	19 Nov 2020 18:30:13
User entered '3'	System	16 Nov 2020 14:04:24
User entered '2'	System	13 Nov 2020 18:20:02
User entered '1'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'USA-US104-2020-MRNA-1273-P301000015'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Teresa'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Tracy'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Becker'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Kowalski'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '6550 Mapleridge Street'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Houston'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '77081'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:19:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
User entered 'US'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered '5'	System	21 Dec 2020 15:59:47
User entered '4'	System	19 Nov 2020 18:30:13
User entered '3'	System	16 Nov 2020 14:04:24
User entered '2'	System	13 Nov 2020 18:20:02
User entered '1'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:09:03

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
User entered '02/Nov/2020 18:42'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:09:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:19:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'USA-US104-2020-MRNA-1273-P301000015'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Teresa'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Tracy'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Becker'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Kowalski'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '6550 Mapleridge Street'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Houston'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '77081'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:19:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
User entered 'US'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered '5'	System	21 Dec 2020 15:59:47
User entered '4'	System	19 Nov 2020 18:30:13
User entered '3'	System	16 Nov 2020 14:04:24
User entered '2'	System	13 Nov 2020 18:20:02
User entered '1'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:09:03

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '13/Nov/2020 18:20'	(b) (4) System	13 Nov 2020 18:20:02

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:09:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:04:14
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 18:20:02

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'USA-US104-2020-MRNA-1273-P301000015'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Teresa'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Tracy'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Becker'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Kowalski'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '6550 Mapleridge Street'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Houston'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '77081'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:19:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
User entered 'US'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered '5'	System	21 Dec 2020 15:59:47
User entered '4'	System	19 Nov 2020 18:30:13
User entered '3'	System	16 Nov 2020 14:04:24
User entered '2'	System	13 Nov 2020 18:20:02
User entered '1'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:09:03

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '16/Nov/2020 09:04'	(b) (4) System	16 Nov 2020 14:04:24

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:09:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:30:01
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 14:04:24

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'USA-US104-2020-MRNA-1273-P301000015'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Teresa'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Tracy'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Becker'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Kowalski'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '6550 Mapleridge Street'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Houston'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '77081'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:19:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
User entered 'US'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered '5'	System	21 Dec 2020 15:59:47
User entered '4'	System	19 Nov 2020 18:30:13
User entered '3'	System	16 Nov 2020 14:04:24
User entered '2'	System	13 Nov 2020 18:20:02
User entered '1'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:09:03

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '19/Nov/2020 18:30'	(b) (4) System	19 Nov 2020 18:30:13

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:09:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:30:13

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'USA-US104-2020-MRNA-1273-P301000015'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Yes (Y)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'No (N)'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Teresa'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Tracy'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:59:47
DataPoint Un-verified.	System	21 Dec 2020 15:59:47
User entered 'Becker'	System	21 Dec 2020 15:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 18:42:35
User entered 'Kowalski'	System	02 Nov 2020 18:41:46

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '6550 Mapleridge Street'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered 'Houston'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '77081'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:19:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 19:16:01
User entered 'US'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
	(b) (4)	
User entered '5'	System	21 Dec 2020 15:59:47
User entered '4'	System	19 Nov 2020 18:30:13
User entered '3'	System	16 Nov 2020 14:04:24
User entered '2'	System	13 Nov 2020 18:20:02
User entered '1'	System	02 Nov 2020 18:42:43

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:09:03

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
User entered '21/Dec/2020 10:59'	(b) (4) System	21 Dec 2020 15:59:47

US3222611

Folder: SAE USA-US104-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:09:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 17:54:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:00:13
User entered '1'	(b) (4), (b) (6)	21 Dec 2020 15:59:47