

US3222452 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:04:07

All time stamps listed in this document are displayed in GMT

US3222452

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

[Participant ID](#)

US3222452

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

US3222452

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Date of Birth (MMM yyyy)	(b) (6) 1939
Age	80
Age Units	YEARS
Age (Derived)	80
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 18:37:16

Generated On: 09 Jun 2021 16:04:07

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 18:37:16

Generated On: 09 Jun 2021 16:04:07

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 18:37:16

Generated On: 09 Jun 2021 16:04:07

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 JAN 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222452

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

Condition	HYPERCHOLESTEROLEMI
Start date (dd MMM yyyy)	01 JAN 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222452

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

Condition	NEUROPATHY
Start date (dd MMM yyyy)	01 JAN 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222452

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

Condition	DEPRESSION
Start date (dd MMM yyyy)	01 JAN 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222452

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:39 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 10:39
Height (<i>xxx.x</i>)	172.7 cm
Weight (<i>xxx.x</i>)	64.8 kg
BMI (<i>xxx.x</i>)	21.72653 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) 22 Feb 2021 18:37:16

Generated On: 09 Jun 2021 16:04:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 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: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Date of assessment (*dd MMM yyyy*) 2 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (*dd MMM yyyy*) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____
Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 18:37:16

Generated On: 09 Jun 2021 16:04:07

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 RETIRED

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) 22 Feb 2021 18:37:16

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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) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

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

What was the participant's randomization number? 189505

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) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

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) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 10:45
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:17
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3222452

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 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) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 SEP 2020

What was the treatment time? (00:00-23:59) 11:45 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 11:45

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

US3222452

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	11:02 (24 HR)
Collection date and time (derived)	2 SEP 2020 11:02

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	2 SEP 2020 11:05
Nasopharyngeal Swab 2	No		

US3222452

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:19

PC Open Date & Time

02 SEP 2020 12:05

PC Close Date & Time

02 SEP 2020 14:35

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 96.8 °F

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

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

PC Time Stamp	03 SEP 2020 07:01
PC Open Date & Time	02 SEP 2020 15:30
PC Close Date & Time	03 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 13:16

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 20:47

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

05 SEP 2020 17:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 17:09

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 05:52

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 18:37

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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

02 SEP 2020 12:20

PC Open Date & Time

02 SEP 2020 12:05

PC Close Date & Time

02 SEP 2020 14:35

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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

03 SEP 2020 07:02

PC Open Date & Time

02 SEP 2020 15:30

PC Close Date & Time

03 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 13:17

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 20:48

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 17:17

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 17:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 05:52

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 18:37

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 12:21
PC Open Date & Time	02 SEP 2020 12:05
PC Close Date & Time	02 SEP 2020 14:35

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 07:04
PC Open Date & Time	02 SEP 2020 15:30
PC Close Date & Time	03 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 2564

EAB) (1725)

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 13:17
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2564

EAB) (1725)

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:49
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2564

EAB) (1725)

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 17:17
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2564

EAB) (1725)

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 17:10
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2564

EAB) (1725)

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 05:53
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 18:38
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3222452

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 10:10
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	11:26 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 11:26
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3222452

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

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.

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 OCT 2020

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 10:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3222452

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 OCT 2020
Collection time (00:00-23:59)	10:30 (24 HR)
Collection date and time (derived)	02 OCT 2020 10:30

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:33	2 OCT 2020 10:33
Nasopharyngeal Swab 2	No		

US3222452

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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

02 OCT 2020 11:35

PC Open Date & Time

02 OCT 2020 11:10

PC Close Date & Time

02 OCT 2020 13:40

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.1 °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	03 OCT 2020 06:07
PC Open Date & Time	02 OCT 2020 14:35
PC Close Date & Time	03 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 16:43

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

05 OCT 2020 06:00

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

05 OCT 2020 18:53

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

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

98.0 °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

06 OCT 2020 18:50

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 18:26

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 19:48

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 11:35

PC Open Date & Time

02 OCT 2020 11:10

PC Close Date & Time

02 OCT 2020 13:40

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 ☐

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

991

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)**

2

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

03 OCT 2020 06:05

PC Open Date & Time

02 OCT 2020 14:35

PC Close Date & Time

03 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

300

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)**

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 16:44

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

300

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)**

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 06:02

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

1

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 18:54

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 18:50

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 18:26

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 19:48

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 11:36
PC Open Date & Time	02 OCT 2020 11:10
PC Close Date & Time	02 OCT 2020 13:40

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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

No ☒

Yes ☐

PC Time stamp	03 OCT 2020 06:08
PC Open Date & Time	02 OCT 2020 14:35
PC Close Date & Time	03 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 16:46
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 06:02
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 18:54
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 18:51
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 18:26
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

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 ☒

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 19:49
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3222452

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

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) _____

US3222452

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

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.

US3222452

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 NOV 2020
Collection time (00:00-23:59)	11:05 (24 HR)
Collection date and time (derived)	5 NOV 2020 11:05

US3222452

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:36

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 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	06 NOV 2020 12:00:42
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 17:59:43

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 12:00:38

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 06:20:43
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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	04 DEC 2020 06:18:13
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

14 DEC 2020 19:01:32

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 12:43:32
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 06:25:34

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 05:38:22
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

09 JAN 2021 10:57:34

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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	15 JAN 2021 08:00:29
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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	26 JAN 2021 13:21:08
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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	29 JAN 2021 13:51:55
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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	07 FEB 2021 12:14:07
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 16:22:50
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 17:01:57

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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	08 MAR 2021 23:08:36
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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	14 MAR 2021 21:23:38
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 MAR 2021 10:00:38
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 15:59:50

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

03 APR 2021 11:40:11

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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	09 APR 2021 17:26:22
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 APR 2021 06:49:36
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 <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	23 APR 2021 15:33:17
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 12:29:16

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 NOV 2021 00:01
Patient Cloud Close Date & Time	09 NOV 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Patient Cloud Open Date & Time	12 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2021 00:01
Patient Cloud Close Date & Time	23 NOV 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2022 00:01
Patient Cloud Close Date & Time	28 JUN 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 ☐

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Date and time of submission	
Patient Cloud Open Date & Time	28 OCT 2022 00:01
Patient Cloud Close Date & Time	01 NOV 2022 23:59

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3222452

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:04:07

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	08 MAR 2021 23:09:06

US3222452

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 21:46:39

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:35:04

Generated On: 09 Jun 2021 16:04:07

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

Visit date (dd MMM yyyy)	31 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 14:35:04

Generated On: 09 Jun 2021 16:04:07

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) _____

US3222452

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

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.

US3222452

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

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

Collection date (dd MMM yyyy)	31 MAR 2021
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Collection time (00:00-23:59)	9:00 (24 HR)
-------------------------------	--------------

Collection date and time (derived)	31 MAR 2021 9:00
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US3222452

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:13:48

Generated On: 09 Jun 2021 16:04:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222452

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:13:48

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222452

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222452

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:04:07

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"/>

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:04:07

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222452

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

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

Visit date (dd MMM yyyy)	22 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3222452

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

Date of updated informed consent (dd MMM yyyy) 22 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 22 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3222452

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

22 JAN 2021 09:40

US3222452

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	09:43
Collection Date and Time (derived)	22 JAN 2021 09:43

US3222452

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

AEID	USA-US104-2020-MRNA-1273-P30 1000014
Adverse event	FALL
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)	26 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)	26 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

THE PATIENT WAS CALLED FOR A DAY 50 SAFETY CALL AND SHE REPORTED SHE FELL AT HOME ON 10/26/20 AND WAS ADMITTED TO THE ICU. SHE STATES SHE FRACTURED HER C3 AND HAS A HEMATOMA AND IS STILL IN ICU. SHE STATES SHE WOULD LIKE TO CONTINUE THE STUDY. WILL SEND FOR MEDICAL RECORDS TODAY FOR FURTHER INFORMATION.

ADMISSION NOTES:
PATIENT WAS TRANSPORTED BY AMBULANCE AFTER LOSING HER FOOTING FROM A STANDING POSITION AT HOME, 8/10 NECK PAIN AND LACERATION TO BACK OF HEAD AND FOREHEAD. EMERGENCY DEPARTMENT

PROCEDURES:
26/OCT/2020 CT MAXILLOFACIAL, CT SPINE CERVICAL, CT HEAD AND BRAIN. CT SCAN OF THE BRAIN AND C-SPINE AND WAS NOTED TO HAVE A TEAR DROP C3 FRACTURES AS WELL AS A SMALL SUBDURAL LEFT PARAFALACINE SUBDURAL HEMATOMA. AND THE CT RULED OUT VESEL INJURIES. NEUROSURGERY WAS

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

CONSULTED "RECCOMENDED
NO SURGINCAL
INTERVENTION" PATIENT
PLACED IN A C-COLLAR. SHE IS
ABLE TO MOVE ALL
EXTREMITIES, NO FOCAL
DEFICITES NOTED. REPEAT CT
HEAD SHOWED WORSENING OF
HEMATOMA. BLOOD PRESSURE
REMAINS STABLE NO SEIZURE
PROPHYLAXIS PER
NEUROSURGERY. PATIENT
NOW STABLE FOR
DOWNGRADE OUT OF THE ICU.
CASE WAS DISCUSSED WITH
CRITICAL CARE INTENSIVIST.
DIAGNOSIS:
SUBDURAL HEMATOMA
C3 CERVICAL FRACTURE
FACIAL LACERATION
NASAL FRACTURE
ADVANCED AGE
ADMITTED TO ICU ON
26/OCT/2020 @ 23:48 AND
DOWNGRADED FROM THE ICU
ON 27/OCT/2020 @ 14:11.
DISCHARGE SUMMARY:
DENIES ANY SHORTNESS OF
BREATH. NO FOCAL DEFICITS
NOTED ON EXAM. ALERT AND
ORIENTED. SHE IS
HEMODYNAMICALLY STABLE.
SINUS BRADYCARDIA HEART
RATE 54. RESPIRATORY
DISTRESS NOTED. SHE DOES

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

HAVE PAIN TO FACE
SECONDARY TO NOSE
FRACTURE AND GENERALIZED
PAIN FROM FALL.
FLEXION-EXTENSION X-RAYS
OF THE CERVICAL SPINE
WITHOUT INSTABILITY.
CONTINUE MIAMI J COLLAR.
DAILY PT AND OT. BLOOD
PRESSURE REMAINED
CONTROLLED. NO FOCAL
DEFICITS. PATIENT WAS
CLEARED BY NEUROSURGERY
FOR DISCHARGE. DISCHARGED
HOME WITH HOME HEALTH
CARE.

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)	1

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

AEID	USA-US104-2020-MRNA-1273-P30 1000014
Adverse event	SUBDURAL HEMATOMA
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)	26 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)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	THE SAE WAS THE MECHANISM OF INJURY AND THIS SUBDURAL HEMATOMA WAS DIAGNOSED FROM A CT OF THE BRAIN.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

1

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

AEID	USA-US104-2020-MRNA-1273-P30 1000014
Adverse event	C3 CERVICAL FRACTURE
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)	26 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)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

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Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PLEASE REFER TO THE FALL AS HER SAE AND THIS C3 CERVICAL FRACTURE WAS A RESULT OF THAT FALL.
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)	1

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Folder: Adverse Events

Form: Adverse Events (4)

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AEID	USA-US104-2020-MRNA-1273-P30 1000014
Adverse event	FACIAL LACERATION
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)	26 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)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	REFER TO PRIMARY SAE: USA-US104-2020-MRNA-1273-P30 1000014. FACIAL LACERATION IS SECONDARY TO THE PRIMARY SAE WHICH IS THE FALL.
Serious Adverse Event Derived (CSA Programming Field Only)	1
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Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

AEID	USA-US104-2020-MRNA-1273-P30 1000014
Adverse event	NASAL FRACTURE
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)	26 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)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Form: Adverse Events (5)

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Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PRIMARY SAE: USA-US104-2020-MRNA-1273-P30 1000014. NASAL FRACTURE IS SECONDARY TO THE PRIMARY SAE "FALL".
Serious Adverse Event Derived (CSA Programming Field Only)	1
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Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 14:35:02

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AEID	
Adverse event	ANXIETY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

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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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____ _____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:35:02

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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)	1 JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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 (2)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY (MOTOR)
(LOWER EXTREMITY)

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:35:02

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		1 JAN 2005
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 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication GLUCOSAMINE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:35:02

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Name of Medication MULTI-VITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication PRESERVISION

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (9)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SORENESS AT INJECTION SITE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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)		03 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication PAIN PRN- CERVICAL SPINE
PAIN, NASAL FRACTURE AND
FACIAL LACERATION
SECONDARY TO FALL

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 2 HOURS/PRN

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:35:02

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 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 (11)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication NORMAL SALINE

Prophylaxis Yes ☒
No ☐

Indication DIHYDRATION - PROPHYLAXIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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 (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 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 (12)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☒
No ☐

Indication DIHYDRATION -

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 (12)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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 (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		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 (13)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication SALINE FLUSH

Prophylaxis Yes ☒
No ☐

Indication LACERATION SECONDARY TO FALL

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

EVERY 12 HOURS/PRN

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		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 (14)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA DUE TO SUBDURAL
HEMATOMA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication ACETAMINOPHEN-HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication SUBDURAL HEMATOMA,
NASAL FRACTURE, AND
FACIAL LACERATION PAIN -
PROPHYLAXIS

Dose per administration 325-5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	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 (16)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication AE # 1
INFECTION PREVENTATIVE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒
No ☐

Indication HEARTBURN PREVENTATIVE

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 (18)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		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"/>

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication NICARDIPINE

Prophylaxis Yes ☐
No ☒

Indication SUBDURAL HEMATOMA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

5MG/HR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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 (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 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 (20)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication LABETALOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (22)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (23)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (23)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 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 (24)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 30

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 (24)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

Name of Medication UNKNOWN DERMAL FILLER

Prophylaxis Yes ☐
No ☒

Indication COSMETIC

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:35:02

Generated On: 09 Jun 2021 16:04:07

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 0000
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"/>

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Feb 2021 18:37:15

Generated On: 09 Jun 2021 16:04:07

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 OCT 2020	CT MAXILLOFACIAL WITHOUT CONTRACET	Adverse Event	
26 OCT 2020	CT CERVIAL SPINE WITHOUT CONTRAST	Adverse Event	
26 OCT 2020	CAT SCAN HEAD AND BRAIN	Adverse Event	
26 OCT 2020	PHYSICAL THERAPY	Adverse Event	
26 OCT 2020	OCCUPATIONAL THERAPY	Adverse Event	
26 OCT 2020	FLEXION EXTENSION X-RAY OF CERVICAL SPINE	Adverse Event	
26 OCT 2020	CERVICAL COLLAR	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:04:07

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

US3222452

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:04:07

Date of study discontinuation/completion (dd MMM yyyy)	
Reason for discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Complete <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Other <input type="checkbox"/>
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 <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other <input type="checkbox"/>
If main cause of death is Other, specify	
Date of death (dd MMM yyyy)	
Was autopsy performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

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Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

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Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	30/OCT/2020 13:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	09/NOV/2020 08:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/NOV/2020 02:13
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

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/NOV/2020 20:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/NOV/2020 21:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	03/DEC/2020 12:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	07/DEC/2020 09:52
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

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/MAR/2021 09:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (9)

Data signed: (b) (4) 26 Apr 2021 14:35:03

Generated On: 09 Jun 2021 16:04:07

SAEID	USA-US104-2020-MRNA-1273-P301000014
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3222452 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222452

Form: Participant Creation

Generated On: 09 Jun 2021 16:04:07

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'US3222452'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:54:56

US3222452

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:41
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	02 Sep 2020 15:50:13

US3222452

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:41
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:54:57

US3222452

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:41
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4) (b) (4)	02 Sep 2020 15:50:13

US3222452

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'SCRN'	System	02 Sep 2020 15:50:13

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered (b) (6) 1939'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:54:58

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered '80'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'YEARS'	System	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '80'	System	02 Sep 2020 15:50:23

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered 'Female (F)'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered 'I'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered '0'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered '0'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered '0'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered '0'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered '0'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered empty.	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered '0'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:07

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:09:47
User entered '0'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:03:14

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '2 Sep 2020'	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:23

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'Sep 2020'	System	02 Sep 2020 15:50:23

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '2020'	System	02 Sep 2020 15:50:23

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Amendment 3 (3)'	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:23

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:23

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:23

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:23

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:23

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:54:57

US3222452

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'I'	System	02 Sep 2020 15:50:27

US3222452

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:27

US3222452

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:04:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:13

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
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.	Coder Import (b) (4)	03 Sep 2020 12:05:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 12:05:44
Data point term sent to Coder	System	03 Sep 2020 12:04:40
User entered 'Hypertension'	Amber Vasquez (b) (4)	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '01 Jan 1980'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:03:41
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'Jan 1980'	System	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '1980'	System	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:04:33

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
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)	03 Sep 2020 12:06:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 12:06:51
Data point term sent to Coder	System	03 Sep 2020 12:05:41
User entered 'Hypercholesterolemi'	Amber Vasquez (b) (4)	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '01 Jan 1980'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'Jan 1980'	System	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '1980'	System	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:04:57

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Query 'Per DM CLR: Please verify the TYPE OF NEUROPATHY (i.e. sensory or motor) and LOCATION (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:07:32
User opened query 'Per DM CLR: Please verify the TYPE OF NEUROPATHY (i.e. sensory or motor) and LOCATION (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).		27 Oct 2020 09:10:52
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 12:06:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 12:06:51
Data point term sent to Coder	System	03 Sep 2020 12:05:41
User entered 'Neuropathy'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '01 Jan 2005'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'Jan 2005'	System	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '2005'	System	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:05:24

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 12:07:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 12:07:59
Data point term sent to Coder	System	03 Sep 2020 12:06:41
User entered 'Depression'	Amber Vasquez (b) (4)	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '01 Jan 1970'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'Jan 1970'	System	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '1970'	System	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:05:47

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 12:10:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 12:10:48
Data point term sent to Coder	System	03 Sep 2020 12:09:44
User entered 'Postmenopausal'	Amber Vasquez (b) (4)	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'I'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	03 Sep 2020 12:09:11

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Skin cosmetic procedure, LLT: Skin cosmetic procedure - version MedDRA\\23.0.	Coder Import (b) (4)	24 Apr 2021 10:21:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Apr 2021 10:21:46
Data point term sent to Coder	System	23 Apr 2021 16:01:13
User entered 'UNKNOWN COSMETIC PROCEDURE'	douglas winter (b) (4)	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4)	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	23 Apr 2021 16:00:23

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '10:39'	Amber Vasquez (b) (4)	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '2 Sep 2020 10:39'	System	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '172.7' cm	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:08:36
DataPoint set to visible.	(b) (4) System	02 Sep 2020 15:50:27

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '64.8' kg	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:08:36
DataPoint set to visible.	(b) (4) System	02 Sep 2020 15:50:27

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '21.72653'	System	03 Sep 2020 12:08:36
DataPoint set to visible.	System	02 Sep 2020 15:50:27

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'kg/m2'	System	03 Sep 2020 12:08:36
DataPoint set to visible.	System	02 Sep 2020 15:50:27

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 09:11:23
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:16:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:16:16
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 17:38:58
User entered '36.6' C	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alicia Cevera (b) (4)	29 Sep 2020 17:16:16
User entered 'Oral (Oral)'	(b) (4)	
	Amber Vasquez (b) (4)	03 Sep 2020 12:08:36
	(b) (4)	

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:16:16
User entered '56'	Alicia Cevera (b) (4)	03 Sep 2020 12:08:36
	(b) (4)	

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'bpm'	System	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:16:16
User entered '16'	Alicia Cevera (b) (4)	03 Sep 2020 12:08:36
	(b) (4)	

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'breaths/min'	System	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:16:16
User entered '117'	Alicia Cevera (b) (4)	03 Sep 2020 12:08:36
	(b) (4)	

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'mmHg'	System	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:16:16
User entered '80'	Alicia Cevera (b) (4)	03 Sep 2020 12:08:36
	(b) (4)	

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'mmHg'	System	03 Sep 2020 12:08:36

US3222452

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52

US3222452

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:07

US3222452

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '2 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:07

US3222452

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '2 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:47

US3222452

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:07

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:47

US3222452

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:07

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:47

US3222452

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:07

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:47

US3222452

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:07

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:47

US3222452

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:07

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:47

US3222452

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:07

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:47

US3222452

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:07

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'I'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:10:47

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'retired'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'I'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '0'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:11:26

US3222452

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:36

US3222452

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	10 Nov 2020 16:34:20
User entered '2 Sep 2020'	(b) (4)	
	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:36
	(b) (4)	

US3222452

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	02 Sep 2020 15:50:36

US3222452

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'VISIT1'	System	02 Sep 2020 15:50:36

US3222452

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:59:54

US3222452

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:07

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '189505'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:59:54

US3222452

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:07

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:59:54

US3222452

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:07

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)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:13:06

US3222452

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:07

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)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:13:06

US3222452

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:07

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:13:06

US3222452

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:13:06

US3222452

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:07

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	Amber Vasquez (b) (4)	03 Sep 2020 12:13:06

US3222452

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:07

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:16:45
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 04:52:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:52:37

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4)	
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:36:45
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4)	29 Sep 2020 17:25:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 13:55:01
	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43
	(b) (4)	

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4)	19 Oct 2020 13:36:47
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 17:25:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4)	29 Sep 2020 17:17:07
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4)	25 Sep 2020 13:55:04
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4)	
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:36:45
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4)	29 Sep 2020 17:25:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 13:55:01
	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43
	(b) (4)	

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4)	19 Oct 2020 13:36:47
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4)	29 Sep 2020 17:25:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:17:07
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:55:04
User entered empty.	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43
	(b) (4)	

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '10:45'	(b) (4) Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '2 Sep 2020 10:45'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '36.6' C	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '55'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'bpm'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '16'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'breaths/min'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '118'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'mmHg'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '80'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'mmHg'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4)	
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:36:45
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4)	29 Sep 2020 17:25:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 13:55:01
	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43
	(b) (4)	

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:36:47
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'CORRECTION COMPLETED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:25:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:17:07
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:55:04
User entered empty.	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '12:17'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '2 Sep 2020 12:17'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '36.6' C	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '54'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'bpm'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '16'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'breaths/min'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '139'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'mmHg'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '85'	Amber Vasquez (b) (4)	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'mmHg'	System	03 Sep 2020 12:14:43

US3222452

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	03 Sep 2020 12:15:13

US3222452

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Sep 2020'	Amber Vasquez (b) (4)	03 Sep 2020 12:15:13

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Jennifer Dittman (b) (4)	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

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)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Jennifer Dittman (b) (4)	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Sep 2020'	Jennifer Dittman (b) (4)	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '11:45'	Jennifer Dittman (b) (4)	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '2 Sep 2020 11:45'	System	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Right Arm (RIGHT ARM)'	Jennifer Dittman (b) (4)	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'ONCE'	System	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 15:51:30

US3222452

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	03 Sep 2020 12:15:43

US3222452

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	03 Sep 2020 12:15:43

US3222452

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '11:02'	Amber Vasquez (b) (4)	03 Sep 2020 12:15:43

US3222452

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '2 Sep 2020 11:02'	System	03 Sep 2020 12:15:43

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:04:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Sep 2020'	Amber Vasquez (b) (4)	03 Sep 2020 12:15:56

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:15:56

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:15:56

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '11:05'	(b) (4) Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:15:56

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '2 Sep 2020 11:05'	System	03 Sep 2020 12:15:56

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:15:56

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	03 Sep 2020 12:15:56

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Amber Vasquez (b) (4)	03 Sep 2020 12:15:56

US3222452

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered empty.	System	03 Sep 2020 12:15:56

US3222452

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	03 Sep 2020 12:16:01

US3222452

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'I'	System	03 Sep 2020 12:16:01

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:19:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'e7fc3896-00f3-4882-9a90-12562a4e78f8' User entered 'Yes (Y)'	System	02 Sep 2020 16:19:52
	System	02 Sep 2020 16:19:52

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:19:14', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'e7fc3896-00f3-4882-9a90-12562a4e78f8' User entered '97.9'	System	02 Sep 2020 16:19:52
	System	02 Sep 2020 16:19:52

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:19:38', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'e7fc3896-00f3-4882-9a90-12562a4e78f8'	System	02 Sep 2020 16:19:52
User entered 'No (N)'	System	02 Sep 2020 16:19:52

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:19:47', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'e7fc3896-00f3-4882-9a90-12562a4e78f8' User entered '02 Sep 2020 12:19'	System	02 Sep 2020 16:19:52
	System	02 Sep 2020 16:19:52

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Sep 2020 12:05'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Sep 2020 14:35'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:01:15', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd12b6be8-d4e4-40a6-9213-f3763d1c3ca7' User entered 'Yes (Y)'	System	03 Sep 2020 11:01:42
	System	03 Sep 2020 11:01:42

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:01:23', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd12b6be8-d4e4-40a6-9213-f3763d1c3ca7' User entered '96.8'	System	03 Sep 2020 11:01:42
	System	03 Sep 2020 11:01:42

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:01:29', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd12b6be8-d4e4-40a6-9213-f3763d1c3ca7' User entered 'No (N)'	System	03 Sep 2020 11:01:42
	System	03 Sep 2020 11:01:42

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:01:39', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd12b6be8-d4e4-40a6-9213-f3763d1c3ca7' User entered '03 Sep 2020 07:01'	System	03 Sep 2020 11:01:42
	System	03 Sep 2020 11:01:42

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Sep 2020 15:30'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 2'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:15:55', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c8019e96-11ce-4388-9f3a-1930965f4363' User entered 'Yes (Y)'	System	03 Sep 2020 17:16:13
	System	03 Sep 2020 17:16:13

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:16:03', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c8019e96-11ce-4388-9f3a-1930965f4363' User entered '97.0'	System	03 Sep 2020 17:16:13
	System	03 Sep 2020 17:16:13

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:16:06', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c8019e96-11ce-4388-9f3a-1930965f4363' User entered 'No (N)'	System	03 Sep 2020 17:16:13
	System	03 Sep 2020 17:16:13

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:16:11', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c8019e96-11ce-4388-9f3a-1930965f4363' User entered '03 Sep 2020 13:16'	System	03 Sep 2020 17:16:13
	System	03 Sep 2020 17:16:13

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 3'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:46:55', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8ce22670-ed2-4788-a1be-478507d7d937'	System	05 Sep 2020 00:47:44
User entered 'Yes (Y)'	System	05 Sep 2020 00:47:44

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:47:31', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8ce22670-ed2-4788-a1be-478507d7d937' User entered '97.7'	System	05 Sep 2020 00:47:44
	System	05 Sep 2020 00:47:44

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:47:36', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8ce22670-ed2-4788-a1be-478507d7d937'	System	05 Sep 2020 00:47:44
User entered 'No (N)'	System	05 Sep 2020 00:47:44

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:47:42', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8ce22670-ed2-4788-a1be-478507d7d937'	System	05 Sep 2020 00:47:44
User entered '04 Sep 2020 20:47'	System	05 Sep 2020 00:47:44

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 4'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:16:17', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '15eb0f52-5f97-49bc-8e4f-265b3a195b5c' User entered 'Yes (Y)'	System	05 Sep 2020 21:16:36
	System	05 Sep 2020 21:16:36

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:16:24', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '15eb0f52-5f97-49bc-8e4f-265b3a195b5c' User entered '97.0'	System	05 Sep 2020 21:16:36
	System	05 Sep 2020 21:16:36

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:16:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '15eb0f52-5f97-49bc-8e4f-265b3a195b5c' User entered 'No (N)'	System	05 Sep 2020 21:16:36
	System	05 Sep 2020 21:16:36

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:16:33', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '15eb0f52-5f97-49bc-8e4f-265b3a195b5c' User entered '05 Sep 2020 17:16'	System	05 Sep 2020 21:16:36
	System	05 Sep 2020 21:16:36

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 5'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:07:55', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd8306fbc-2f64-4fb8-afef-ec597340334b' User entered 'Yes (Y)'	System	06 Sep 2020 21:09:53
	System	06 Sep 2020 21:09:53

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:09:42', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd8306fbc-2f64-4fb8-afef-ec597340334b' User entered '98.3'	System	06 Sep 2020 21:09:53
	System	06 Sep 2020 21:09:53

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:09:46', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd8306fbc-2f64-4fb8-afef-ec597340334b' User entered 'No (N)'	System	06 Sep 2020 21:09:53
	System	06 Sep 2020 21:09:53

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:09:51', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd8306fbc-2f64-4fb8-afef-ec597340334b' User entered '06 Sep 2020 17:09'	System	06 Sep 2020 21:09:53
	System	06 Sep 2020 21:09:53

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 6'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:05', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5b7089b5-b5e7-41d6-8d98-8253dc55c91a' User entered 'Yes (Y)'	System	08 Sep 2020 09:52:22
	System	08 Sep 2020 09:52:22

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:10', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5b7089b5-b5e7-41d6-8d98-8253dc55c91a' User entered '97.6'	System	08 Sep 2020 09:52:22
	System	08 Sep 2020 09:52:22

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:13', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5b7089b5-b5e7-41d6-8d98-8253dc55c91a' User entered 'No (N)'	System	08 Sep 2020 09:52:22
	System	08 Sep 2020 09:52:22

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:18', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5b7089b5-b5e7-41d6-8d98-8253dc55c91a' User entered '08 Sep 2020 05:52'	System	08 Sep 2020 09:52:22
	System	08 Sep 2020 09:52:22

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 7'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:23', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '4a9d7af2-9991-4061-b0fe-17254a6079e0' User entered 'Yes (Y)'	System	08 Sep 2020 22:37:38
	System	08 Sep 2020 22:37:38

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:29', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '4a9d7af2-9991-4061-b0fe-17254a6079e0' User entered '98.4'	System	08 Sep 2020 22:37:38
	System	08 Sep 2020 22:37:38

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:33', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '4a9d7af2-9991-4061-b0fe-17254a6079e0' User entered 'No (N)'	System	08 Sep 2020 22:37:38
	System	08 Sep 2020 22:37:38

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:37', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '4a9d7af2-9991-4061-b0fe-17254a6079e0' User entered '08 Sep 2020 18:37'	System	08 Sep 2020 22:37:38
	System	08 Sep 2020 22:37:38

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:20:09', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '14998e30-18c2-4563-af7c-fd49c50b5985' User entered 'None (1)'	System	02 Sep 2020 16:21:03
	System	02 Sep 2020 16:21:03

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:20:41', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '14998e30-18c2-4563-af7c-fd49c50b5985' User entered 'No (N)'	System	02 Sep 2020 16:21:03
	System	02 Sep 2020 16:21:03

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:20:45', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '14998e30-18c2-4563-af7c-fd49c50b5985' User entered 'No (N)'	System	02 Sep 2020 16:21:03
	System	02 Sep 2020 16:21:03

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:20:53', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '14998e30-18c2-4563-af7c-fd49c50b5985'	System	02 Sep 2020 16:21:03
User entered 'None (1)'	System	02 Sep 2020 16:21:03

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:20:59', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '14998e30-18c2-4563-af7c-fd49c50b5985' User entered '02 Sep 2020 12:20'	System	02 Sep 2020 16:21:03
	System	02 Sep 2020 16:21:03

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Sep 2020 12:05'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Sep 2020 14:35'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:01:54', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a6f3cd4b-6d78-4f7e-9cdf-881526ec7104'	System	03 Sep 2020 11:03:01
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 11:03:01

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:02:09', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a6f3cd4b-6d78-4f7e-9cdf-881526ec7104'	System	03 Sep 2020 11:03:01
User entered 'No (N)'	System	03 Sep 2020 11:03:01

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:02:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a6f3cd4b-6d78-4f7e-9cdf-881526ec7104'	System	03 Sep 2020 11:03:01
User entered 'No (N)'	System	03 Sep 2020 11:03:01

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:02:47', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a6f3cd4b-6d78-4f7e-9cdf-881526ec7104'	System	03 Sep 2020 11:03:01
User entered 'None (1)'	System	03 Sep 2020 11:03:01

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:02:59', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a6f3cd4b-6d78-4f7e-9cdf-881526ec7104' User entered '03 Sep 2020 07:02'	System	03 Sep 2020 11:03:01
	System	03 Sep 2020 11:03:01

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Sep 2020 15:30'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 2'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:16:29', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '40be5fcc-c09a-4656-901d-a944cfe04b9d' User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 17:17:13
	System	03 Sep 2020 17:17:13

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:16:39', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '40be5fcc-c09a-4656-901d-a944cfe04b9d' User entered 'No (N)'	System	03 Sep 2020 17:17:13
	System	03 Sep 2020 17:17:13

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:16:52', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '40be5fcc-c09a-4656-901d-a944cfe04b9d' User entered 'No (N)'	System	03 Sep 2020 17:17:13
	System	03 Sep 2020 17:17:13

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:02', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '40be5fcc-c09a-4656-901d-a944cfe04b9d' User entered 'None (1)'	System	03 Sep 2020 17:17:13
	System	03 Sep 2020 17:17:13

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:10', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '40be5fcc-c09a-4656-901d-a944cfe04b9d' User entered '03 Sep 2020 13:17'	System	03 Sep 2020 17:17:13
	System	03 Sep 2020 17:17:13

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 3'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:47:55', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'fe4f361d-7353-4068-9c19-37c04832d7e4'	System	05 Sep 2020 00:48:51
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 00:48:51

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:48:05', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'fe4f361d-7353-4068-9c19-37c04832d7e4' User entered 'No (N)'	System	05 Sep 2020 00:48:51
	System	05 Sep 2020 00:48:51

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:48:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'fe4f361d-7353-4068-9c19-37c04832d7e4' User entered 'No (N)'	System	05 Sep 2020 00:48:51
	System	05 Sep 2020 00:48:51

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:48:38', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'fe4f361d-7353-4068-9c19-37c04832d7e4' User entered 'None (1)'	System	05 Sep 2020 00:48:51
	System	05 Sep 2020 00:48:51

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:48:47', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'fe4f361d-7353-4068-9c19-37c04832d7e4' User entered '04 Sep 2020 20:48'	System	05 Sep 2020 00:48:51
	System	05 Sep 2020 00:48:51

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 4'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:16:41', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'befadf85-605a-404a-bfae-82ca68849fd1'	System	05 Sep 2020 21:17:07
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 21:17:07

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:16:45', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'befadf85-605a-404a-bfae-82ca68849fd1' User entered 'No (N)'	System	05 Sep 2020 21:17:07
	System	05 Sep 2020 21:17:07

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:16:57', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'befadf85-605a-404a-bfae-82ca68849fd1' User entered 'No (N)'	System	05 Sep 2020 21:17:07
	System	05 Sep 2020 21:17:07

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:01', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'befadf85-605a-404a-bfae-82ca68849fd1' User entered 'None (1)'	System	05 Sep 2020 21:17:07
	System	05 Sep 2020 21:17:07

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:04', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'befadf85-605a-404a-bfae-82ca68849fd1' User entered '05 Sep 2020 17:17'	System	05 Sep 2020 21:17:07
	System	05 Sep 2020 21:17:07

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 5'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:09:57', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f1709f82-265b-4675-b1ee-0fdb9d5d2823' User entered 'None (1)'	System	06 Sep 2020 21:10:19
	System	06 Sep 2020 21:10:19

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f1709f82-265b-4675-b1ee-0fdb9d5d2823' User entered 'No (N)'	System	06 Sep 2020 21:10:19
	System	06 Sep 2020 21:10:19

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f1709f82-265b-4675-b1ee-0fdb9d5d2823' User entered 'No (N)'	System	06 Sep 2020 21:10:19
	System	06 Sep 2020 21:10:19

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:12', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f1709f82-265b-4675-b1ee-0fdb9d5d2823' User entered 'None (1)'	System	06 Sep 2020 21:10:19
	System	06 Sep 2020 21:10:19

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:16', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f1709f82-265b-4675-b1ee-0fdb9d5d2823' User entered '06 Sep 2020 17:10'	System	06 Sep 2020 21:10:19
	System	06 Sep 2020 21:10:19

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 6'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '1cec3b50-66ab-47e5-b301-91bd8110656f' User entered 'None (1)'	System	08 Sep 2020 09:52:40
	System	08 Sep 2020 09:52:40

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:26', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '1cec3b50-66ab-47e5-b301-91bd8110656f' User entered 'No (N)'	System	08 Sep 2020 09:52:40
	System	08 Sep 2020 09:52:40

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:32', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '1cec3b50-66ab-47e5-b301-91bd8110656f' User entered 'No (N)'	System	08 Sep 2020 09:52:40
	System	08 Sep 2020 09:52:40

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:35', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '1cec3b50-66ab-47e5-b301-91bd8110656f' User entered 'None (1)'	System	08 Sep 2020 09:52:40
	System	08 Sep 2020 09:52:40

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:38', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '1cec3b50-66ab-47e5-b301-91bd8110656f' User entered '08 Sep 2020 05:52'	System	08 Sep 2020 09:52:40
	System	08 Sep 2020 09:52:40

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 7'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:41', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '04a48c8b-baa5-438c-b0b1-e4086e9dc363' User entered 'None (1)'	System	08 Sep 2020 22:37:57
	System	08 Sep 2020 22:37:57

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:44', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '04a48c8b-baa5-438c-b0b1-e4086e9dc363' User entered 'No (N)'	System	08 Sep 2020 22:37:57
	System	08 Sep 2020 22:37:57

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:46', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '04a48c8b-baa5-438c-b0b1-e4086e9dc363' User entered 'No (N)'	System	08 Sep 2020 22:37:57
	System	08 Sep 2020 22:37:57

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:49', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '04a48c8b-baa5-438c-b0b1-e4086e9dc363' User entered 'None (1)'	System	08 Sep 2020 22:37:57
	System	08 Sep 2020 22:37:57

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:52', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '04a48c8b-baa5-438c-b0b1-e4086e9dc363' User entered '08 Sep 2020 18:37'	System	08 Sep 2020 22:37:57
	System	08 Sep 2020 22:37:57

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:21:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'defde309-e54b-4a42-ab96-33b86b66b06b' User entered 'None (0)'	System	02 Sep 2020 16:21:41
	System	02 Sep 2020 16:21:41

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:21:14', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'defde309-e54b-4a42-ab96-33b86b66b06b' User entered 'None (0)'	System	02 Sep 2020 16:21:41
	System	02 Sep 2020 16:21:41

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:21:19', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'defde309-e54b-4a42-ab96-33b86b66b06b' User entered 'None (0)'	System	02 Sep 2020 16:21:41
	System	02 Sep 2020 16:21:41

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:21:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'defde309-e54b-4a42-ab96-33b86b66b06b' User entered 'None (0)'	System	02 Sep 2020 16:21:41
	System	02 Sep 2020 16:21:41

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:21:26', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'defde309-e54b-4a42-ab96-33b86b66b06b' User entered 'None (0)'	System	02 Sep 2020 16:21:41
	System	02 Sep 2020 16:21:41

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:21:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'defde309-e54b-4a42-ab96-33b86b66b06b' User entered 'None (0)'	System	02 Sep 2020 16:21:41
	System	02 Sep 2020 16:21:41

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:21:36', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'defde309-e54b-4a42-ab96-33b86b66b06b' User entered 'No (N)'	System	02 Sep 2020 16:21:41
	System	02 Sep 2020 16:21:41

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-02T12:21:39', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'defde309-e54b-4a42-ab96-33b86b66b06b' User entered '02 Sep 2020 12:21'	System	02 Sep 2020 16:21:41
	System	02 Sep 2020 16:21:41

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Sep 2020 12:05'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Sep 2020 14:35'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:03:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0f7fb2f4-b019-4801-9c8b-92552f9b5eae' User entered 'No interference with activity (1)'	System	03 Sep 2020 11:04:11
	System	03 Sep 2020 11:04:11

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:03:20', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0f7fb2f4-b019-4801-9c8b-92552f9b5eae' User entered 'None (0)'	System	03 Sep 2020 11:04:11
	System	03 Sep 2020 11:04:11

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:03:30', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0f7fb2f4-b019-4801-9c8b-92552f9b5eae' User entered 'None (0)'	System	03 Sep 2020 11:04:11
	System	03 Sep 2020 11:04:11

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:03:40', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0f7fb2f4-b019-4801-9c8b-92552f9b5eae' User entered 'None (0)'	System	03 Sep 2020 11:04:11
	System	03 Sep 2020 11:04:11

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:03:44', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0f7fb2f4-b019-4801-9c8b-92552f9b5eae' User entered 'None (0)'	System	03 Sep 2020 11:04:11
	System	03 Sep 2020 11:04:11

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:03:52', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0f7fb2f4-b019-4801-9c8b-92552f9b5eae' User entered 'None (0)'	System	03 Sep 2020 11:04:11
	System	03 Sep 2020 11:04:11

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:03:57', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0f7fb2f4-b019-4801-9c8b-92552f9b5eae' User entered 'No (N)'	System	03 Sep 2020 11:04:11
	System	03 Sep 2020 11:04:11

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T07:04:09', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0f7fb2f4-b019-4801-9c8b-92552f9b5eae' User entered '03 Sep 2020 07:04'	System	03 Sep 2020 11:04:11
	System	03 Sep 2020 11:04:11

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Sep 2020 15:30'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 2'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:17', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a8710c13-f8e3-4c0b-8b8f-60257b7255f4' User entered 'None (0)'	System	03 Sep 2020 17:17:46
	System	03 Sep 2020 17:17:46

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a8710c13-f8e3-4c0b-8b8f-60257b7255f4' User entered 'None (0)'	System	03 Sep 2020 17:17:46
	System	03 Sep 2020 17:17:46

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:25', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a8710c13-f8e3-4c0b-8b8f-60257b7255f4' User entered 'None (0)'	System	03 Sep 2020 17:17:46
	System	03 Sep 2020 17:17:46

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a8710c13-f8e3-4c0b-8b8f-60257b7255f4' User entered 'None (0)'	System	03 Sep 2020 17:17:46
	System	03 Sep 2020 17:17:46

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:31', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a8710c13-f8e3-4c0b-8b8f-60257b7255f4' User entered 'None (0)'	System	03 Sep 2020 17:17:46
	System	03 Sep 2020 17:17:46

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:33', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a8710c13-f8e3-4c0b-8b8f-60257b7255f4' User entered 'None (0)'	System	03 Sep 2020 17:17:46
	System	03 Sep 2020 17:17:46

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:40', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a8710c13-f8e3-4c0b-8b8f-60257b7255f4' User entered 'No (N)'	System	03 Sep 2020 17:17:46
	System	03 Sep 2020 17:17:46

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-03T13:17:43', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a8710c13-f8e3-4c0b-8b8f-60257b7255f4' User entered '03 Sep 2020 13:17'	System	03 Sep 2020 17:17:46
	System	03 Sep 2020 17:17:46

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 3'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:48:54', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '99272fed-2e40-404d-b0d6-3605c31ced04'	System	05 Sep 2020 00:49:38
User entered 'No interference with activity (1)'	System	05 Sep 2020 00:49:38

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:49:01', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '99272fed-2e40-404d-b0d6-3605c31ced04'	System	05 Sep 2020 00:49:38
User entered 'No interference with activity (1)'	System	05 Sep 2020 00:49:38

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:49:04', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '99272fed-2e40-404d-b0d6-3605c31ced04' User entered 'None (0)'	System	05 Sep 2020 00:49:38
	System	05 Sep 2020 00:49:38

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:49:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '99272fed-2e40-404d-b0d6-3605c31ced04' User entered 'None (0)'	System	05 Sep 2020 00:49:38
	System	05 Sep 2020 00:49:38

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:49:16', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '99272fed-2e40-404d-b0d6-3605c31ced04'	System	05 Sep 2020 00:49:38
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Sep 2020 00:49:38

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:49:19', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '99272fed-2e40-404d-b0d6-3605c31ced04' User entered 'None (0)'	System	05 Sep 2020 00:49:38
	System	05 Sep 2020 00:49:38

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:49:24', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '99272fed-2e40-404d-b0d6-3605c31ced04' User entered 'No (N)'	System	05 Sep 2020 00:49:38
	System	05 Sep 2020 00:49:38

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-04T20:49:35', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '99272fed-2e40-404d-b0d6-3605c31ced04' User entered '04 Sep 2020 20:49'	System	05 Sep 2020 00:49:38
	System	05 Sep 2020 00:49:38

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 4'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:11', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '883a2ef0-96b9-45c7-8efa-9e979d65605c' User entered 'None (0)'	System	05 Sep 2020 21:17:37
	System	05 Sep 2020 21:17:37

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:13', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '883a2ef0-96b9-45c7-8efa-9e979d65605c' User entered 'None (0)'	System	05 Sep 2020 21:17:37
	System	05 Sep 2020 21:17:37

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:16', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '883a2ef0-96b9-45c7-8efa-9e979d65605c' User entered 'None (0)'	System	05 Sep 2020 21:17:37
	System	05 Sep 2020 21:17:37

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:18', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '883a2ef0-96b9-45c7-8efa-9e979d65605c' User entered 'None (0)'	System	05 Sep 2020 21:17:37
	System	05 Sep 2020 21:17:37

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:21', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '883a2ef0-96b9-45c7-8efa-9e979d65605c' User entered 'None (0)'	System	05 Sep 2020 21:17:37
	System	05 Sep 2020 21:17:37

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:23', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '883a2ef0-96b9-45c7-8efa-9e979d65605c' User entered 'None (0)'	System	05 Sep 2020 21:17:37
	System	05 Sep 2020 21:17:37

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:26', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '883a2ef0-96b9-45c7-8efa-9e979d65605c' User entered 'No (N)'	System	05 Sep 2020 21:17:37
	System	05 Sep 2020 21:17:37

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-05T17:17:33', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '883a2ef0-96b9-45c7-8efa-9e979d65605c' User entered '05 Sep 2020 17:17'	System	05 Sep 2020 21:17:37
	System	05 Sep 2020 21:17:37

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 5'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd559a0fc-30df-4574-9d2f-a1a9b5e42e33' User entered 'None (0)'	System	06 Sep 2020 21:10:49
	System	06 Sep 2020 21:10:49

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:31', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd559a0fc-30df-4574-9d2f-a1a9b5e42e33' User entered 'None (0)'	System	06 Sep 2020 21:10:49
	System	06 Sep 2020 21:10:49

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:33', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd559a0fc-30df-4574-9d2f-a1a9b5e42e33' User entered 'None (0)'	System	06 Sep 2020 21:10:49
	System	06 Sep 2020 21:10:49

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:36', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd559a0fc-30df-4574-9d2f-a1a9b5e42e33' User entered 'None (0)'	System	06 Sep 2020 21:10:49
	System	06 Sep 2020 21:10:49

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:38', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd559a0fc-30df-4574-9d2f-a1a9b5e42e33' User entered 'None (0)'	System	06 Sep 2020 21:10:49
	System	06 Sep 2020 21:10:49

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:40', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd559a0fc-30df-4574-9d2f-a1a9b5e42e33' User entered 'None (0)'	System	06 Sep 2020 21:10:49
	System	06 Sep 2020 21:10:49

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:43', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd559a0fc-30df-4574-9d2f-a1a9b5e42e33'	System	06 Sep 2020 21:10:49
User entered 'No (N)'	System	06 Sep 2020 21:10:49

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-06T17:10:46', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd559a0fc-30df-4574-9d2f-a1a9b5e42e33'	System	06 Sep 2020 21:10:49
User entered '06 Sep 2020 17:10'	System	06 Sep 2020 21:10:49

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 6'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:47', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c51273e7-b0e0-4396-a348-e534ed6747be'	System	08 Sep 2020 09:53:13
User entered 'No interference with activity (1)'	System	08 Sep 2020 09:53:13

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:50', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c51273e7-b0e0-4396-a348-e534ed6747be' User entered 'None (0)'	System	08 Sep 2020 09:53:13
	System	08 Sep 2020 09:53:13

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:52', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c51273e7-b0e0-4396-a348-e534ed6747be' User entered 'None (0)'	System	08 Sep 2020 09:53:13
	System	08 Sep 2020 09:53:13

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:55', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c51273e7-b0e0-4396-a348-e534ed6747be' User entered 'None (0)'	System	08 Sep 2020 09:53:13
	System	08 Sep 2020 09:53:13

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:52:57', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c51273e7-b0e0-4396-a348-e534ed6747be' User entered 'None (0)'	System	08 Sep 2020 09:53:13
	System	08 Sep 2020 09:53:13

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:53:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c51273e7-b0e0-4396-a348-e534ed6747be' User entered 'None (0)'	System	08 Sep 2020 09:53:13
	System	08 Sep 2020 09:53:13

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:53:05', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c51273e7-b0e0-4396-a348-e534ed6747be' User entered 'No (N)'	System	08 Sep 2020 09:53:13
	System	08 Sep 2020 09:53:13

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T05:53:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c51273e7-b0e0-4396-a348-e534ed6747be' User entered '08 Sep 2020 05:53'	System	08 Sep 2020 09:53:13
	System	08 Sep 2020 09:53:13

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 7'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:37:58', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '44c2e3f1-99d6-46ee-a2e4-000f0ab47d63' User entered 'None (0)'	System	08 Sep 2020 22:38:17
	System	08 Sep 2020 22:38:17

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:38:01', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '44c2e3f1-99d6-46ee-a2e4-000f0ab47d63' User entered 'None (0)'	System	08 Sep 2020 22:38:17
	System	08 Sep 2020 22:38:17

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:38:02', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '44c2e3f1-99d6-46ee-a2e4-000f0ab47d63' User entered 'None (0)'	System	08 Sep 2020 22:38:17
	System	08 Sep 2020 22:38:17

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:38:05', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '44c2e3f1-99d6-46ee-a2e4-000f0ab47d63' User entered 'None (0)'	System	08 Sep 2020 22:38:17
	System	08 Sep 2020 22:38:17

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:38:06', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '44c2e3f1-99d6-46ee-a2e4-000f0ab47d63' User entered 'None (0)'	System	08 Sep 2020 22:38:17
	System	08 Sep 2020 22:38:17

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:38:09', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '44c2e3f1-99d6-46ee-a2e4-000f0ab47d63' User entered 'None (0)'	System	08 Sep 2020 22:38:17
	System	08 Sep 2020 22:38:17

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:38:12', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '44c2e3f1-99d6-46ee-a2e4-000f0ab47d63' User entered 'No (N)'	System	08 Sep 2020 22:38:17
	System	08 Sep 2020 22:38:17

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-09-08T18:38:15', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '44c2e3f1-99d6-46ee-a2e4-000f0ab47d63' User entered '08 Sep 2020 18:38'	System	08 Sep 2020 22:38:17
	System	08 Sep 2020 22:38:17

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 15:51:30

US3222452

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:32:29

US3222452

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '09 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 16:33:40
User entered '9 Sep 2020'	Alicia Cevera (b) (4)	29 Sep 2020 17:32:29

US3222452

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:32:29

US3222452

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:32:29

US3222452

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:32:38

US3222452

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'I'	System	29 Sep 2020 17:32:38

US3222452

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	02 Oct 2020 15:28:50

US3222452

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '16 Sep 2020'	Crystal Paccione (b) (4)	02 Oct 2020 15:28:50

US3222452

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	02 Oct 2020 15:28:50

US3222452

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Crystal Paccione (b) (4)	02 Oct 2020 15:28:50

US3222452

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:32:47

US3222452

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User entered 'I'	System	29 Sep 2020 17:32:47

US3222452

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:33:14

US3222452

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '24 Sep 2020'	Alicia Cevera (b) (4)	29 Sep 2020 17:33:14

US3222452

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:33:14

US3222452

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:33:14

US3222452

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:33:21

US3222452

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:03
User entered 'I'	System	29 Sep 2020 17:33:21

US3222452

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	02 Oct 2020 15:29:08

US3222452

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Oct 2020'	(b) (4) Crystal Paccione (b) (4)	02 Oct 2020 15:29:08

US3222452

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Clinic (Clinic)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	02 Oct 2020 15:29:08

US3222452

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'VISIT2'	System	02 Oct 2020 15:29:08

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User accepted default value 'Pre-Dose (PREDOSE)'	Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '10:10'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '2 Oct 2020 10:10'	System	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '36.7' C	Alicia Cevera (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Oral (Oral)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '51'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'bpm'	System	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '16'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'breaths/min'	System	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '112'	Alicia Cevera (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'mmHg'	System	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '76'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'mmHg'	System	19 Oct 2020 12:25:15

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User accepted default value 'Post-Dose (POSTDOSE)'	Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '11:26'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '2 Oct 2020 11:26'	System	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '36.6' C	Alicia Cevera (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Oral (Oral)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '49'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'bpm'	System	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '16'	Alicia Cevera (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'breaths/min'	System	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '130'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'mmHg'	System	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '84'	Alicia Cevera (b) (4)	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'mmHg'	System	19 Oct 2020 12:27:47

US3222452

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:31:12

US3222452

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Alicia Cevera (b) (4)	19 Oct 2020 12:31:12

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	(b) (4) Crystal Paccione (b) (4)	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

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)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Crystal Paccione (b) (4)	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Oct 2020'	Crystal Paccione (b) (4)	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '10:50'	(b) (4) Crystal Paccione (b) (4)	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '2 Oct 2020 10:50'	System	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Crystal Paccione (b) (4)	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'ONCE'	System	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 15:29:31

US3222452

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:31:48

US3222452

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '02 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:31:48

US3222452

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '10:30'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:31:48

US3222452

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '02 Oct 2020 10:30'	System	19 Oct 2020 12:31:48

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:04:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '2 Oct 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:32:13

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:32:13

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:32:13

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '10:33'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:32:13

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '2 Oct 2020 10:33'	System	19 Oct 2020 12:32:13

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:32:13

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:32:13

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Alicia Cevera (b) (4)	19 Oct 2020 12:32:13

US3222452

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered empty.	System	19 Oct 2020 12:32:13

US3222452

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	19 Oct 2020 12:32:19

US3222452

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '1'	System	19 Oct 2020 12:32:19

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:34:45', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '58e6580d-d8fc-47ef-a8c1-854c80c8906f' User entered 'Yes (Y)'	System	02 Oct 2020 15:35:11
	System	02 Oct 2020 15:35:11

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:34:51', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '58e6580d-d8fc-47ef-a8c1-854c80c8906f' User entered '98.0'	System	02 Oct 2020 15:35:11
	System	02 Oct 2020 15:35:11

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:34:58', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '58e6580d-d8fc-47ef-a8c1-854c80c8906f' User entered 'No (N)'	System	02 Oct 2020 15:35:11
	System	02 Oct 2020 15:35:11

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '58e6580d-d8fc-47ef-a8c1-854c80c8906f' User entered '02 Oct 2020 11:35'	System	02 Oct 2020 15:35:11
	System	02 Oct 2020 15:35:11

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Oct 2020 11:10'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Oct 2020 13:40'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:07:01', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c1158bd2-33c8-4b8a-b904-00cd25e7fee6' User entered 'Yes (Y)'	System	03 Oct 2020 10:07:23
	System	03 Oct 2020 10:07:23

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:07:07', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c1158bd2-33c8-4b8a-b904-00cd25e7fee6' User entered '99.1'	System	03 Oct 2020 10:07:23
	System	03 Oct 2020 10:07:23

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:07:12', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c1158bd2-33c8-4b8a-b904-00cd25e7fee6' User entered 'No (N)'	System	03 Oct 2020 10:07:23
	System	03 Oct 2020 10:07:23

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:07:21', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c1158bd2-33c8-4b8a-b904-00cd25e7fee6' User entered '03 Oct 2020 06:07'	System	03 Oct 2020 10:07:23
	System	03 Oct 2020 10:07:23

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Oct 2020 14:35'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 2'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:43:16', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '3900c94d-2044-4d07-ad93-f57d32fa164c' User entered 'Yes (Y)'	System	03 Oct 2020 20:43:42
	System	03 Oct 2020 20:43:42

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:43:25', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '3900c94d-2044-4d07-ad93-f57d32fa164c' User entered '100.6'	System	03 Oct 2020 20:43:42
	System	03 Oct 2020 20:43:42

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:43:30', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '3900c94d-2044-4d07-ad93-f57d32fa164c' User entered 'No (N)'	System	03 Oct 2020 20:43:42
	System	03 Oct 2020 20:43:42

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:43:37', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '3900c94d-2044-4d07-ad93-f57d32fa164c' User entered '03 Oct 2020 16:43'	System	03 Oct 2020 20:43:42
	System	03 Oct 2020 20:43:42

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 3'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:00:32', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a52e014c-89a0-44dc-b855-6e4234c8911a' User entered 'Yes (Y)'	System	05 Oct 2020 10:00:54
	System	05 Oct 2020 10:00:54

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:00:37', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a52e014c-89a0-44dc-b855-6e4234c8911a' User entered '98.1'	System	05 Oct 2020 10:00:54
	System	05 Oct 2020 10:00:54

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:00:46', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a52e014c-89a0-44dc-b855-6e4234c8911a' User entered 'No (N)'	System	05 Oct 2020 10:00:54
	System	05 Oct 2020 10:00:54

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:00:51', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a52e014c-89a0-44dc-b855-6e4234c8911a' User entered '05 Oct 2020 06:00'	System	05 Oct 2020 10:00:54
	System	05 Oct 2020 10:00:54

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 4'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:52:45', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8bd05060-094a-4d84-8085-b37f4cd6fe5f' User entered 'Yes (Y)'	System	05 Oct 2020 22:53:06
	System	05 Oct 2020 22:53:06

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:52:51', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8bd05060-094a-4d84-8085-b37f4cd6fe5f' User entered '97.0'	System	05 Oct 2020 22:53:06
	System	05 Oct 2020 22:53:06

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:52:57', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8bd05060-094a-4d84-8085-b37f4cd6fe5f' User entered 'No (N)'	System	05 Oct 2020 22:53:06
	System	05 Oct 2020 22:53:06

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:53:02', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8bd05060-094a-4d84-8085-b37f4cd6fe5f' User entered '05 Oct 2020 18:53'	System	05 Oct 2020 22:53:06
	System	05 Oct 2020 22:53:06

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 5'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:17', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0a9e24ea-5d2e-44a4-9761-8b9b7043c0c0' User entered 'Yes (Y)'	System	06 Oct 2020 22:50:34
	System	06 Oct 2020 22:50:34

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0a9e24ea-5d2e-44a4-9761-8b9b7043c0c0' User entered '98.0'	System	06 Oct 2020 22:50:34
	System	06 Oct 2020 22:50:34

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:27', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0a9e24ea-5d2e-44a4-9761-8b9b7043c0c0' User entered 'No (N)'	System	06 Oct 2020 22:50:34
	System	06 Oct 2020 22:50:34

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:31', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '0a9e24ea-5d2e-44a4-9761-8b9b7043c0c0' User entered '06 Oct 2020 18:50'	System	06 Oct 2020 22:50:34
	System	06 Oct 2020 22:50:34

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 6'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:25:50', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '382f6227-d207-4e73-a2fa-0da5e79ab3e6' User entered 'Yes (Y)'	System	07 Oct 2020 22:26:08
	System	07 Oct 2020 22:26:08

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:25:55', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '382f6227-d207-4e73-a2fa-0da5e79ab3e6' User entered '98.0'	System	07 Oct 2020 22:26:08
	System	07 Oct 2020 22:26:08

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:25:59', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '382f6227-d207-4e73-a2fa-0da5e79ab3e6' User entered 'No (N)'	System	07 Oct 2020 22:26:08
	System	07 Oct 2020 22:26:08

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:04', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '382f6227-d207-4e73-a2fa-0da5e79ab3e6' User entered '07 Oct 2020 18:26'	System	07 Oct 2020 22:26:08
	System	07 Oct 2020 22:26:08

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 7'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:45:56', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7e8b1b28-a882-40c4-af55-d16e2f3fec4c' User entered 'Yes (Y)'	System	08 Oct 2020 23:48:39
	System	08 Oct 2020 23:48:39

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:48:24', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7e8b1b28-a882-40c4-af55-d16e2f3fec4c' User entered '96.9'	System	08 Oct 2020 23:48:39
	System	08 Oct 2020 23:48:39

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:48:29', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7e8b1b28-a882-40c4-af55-d16e2f3fec4c' User entered 'No (N)'	System	08 Oct 2020 23:48:39
	System	08 Oct 2020 23:48:39

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:48:34', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7e8b1b28-a882-40c4-af55-d16e2f3fec4c' User entered '08 Oct 2020 19:48'	System	08 Oct 2020 23:48:39
	System	08 Oct 2020 23:48:39

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6f81de44-466d-4732-ae93-fbd18d69afe7'	System	02 Oct 2020 15:35:39
User entered 'None (1)'	System	02 Oct 2020 15:35:39

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:25', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6f81de44-466d-4732-ae93-fbd18d69afe7' User entered 'No (N)'	System	02 Oct 2020 15:35:39
	System	02 Oct 2020 15:35:39

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:27', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6f81de44-466d-4732-ae93-fbd18d69afe7' User entered 'No (N)'	System	02 Oct 2020 15:35:39
	System	02 Oct 2020 15:35:39

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:30', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6f81de44-466d-4732-ae93-fbd18d69afe7' User entered 'None (1)'	System	02 Oct 2020 15:35:39
	System	02 Oct 2020 15:35:39

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:35', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6f81de44-466d-4732-ae93-fbd18d69afe7' User entered '02 Oct 2020 11:35'	System	02 Oct 2020 15:35:39
	System	02 Oct 2020 15:35:39

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Oct 2020 11:10'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Oct 2020 13:40'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T05:58:56', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '01546f3c-8fcb-4086-9e6e-a56d7a6e111a'	System	03 Oct 2020 10:05:37
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 10:05:37

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T05:59:09', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '01546f3c-8fcb-4086-9e6e-a56d7a6e111a' User entered 'Yes (Y)'	System	03 Oct 2020 10:05:37
	System	03 Oct 2020 10:05:37

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:01:51', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '01546f3c-8fcb-4086-9e6e-a56d7a6e111a' User entered '991'	System	03 Oct 2020 10:05:37
	System	03 Oct 2020 10:05:37

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:02:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '01546f3c-8fcb-4086-9e6e-a56d7a6e111a' User entered 'Yes (Y)'	System	03 Oct 2020 10:05:37
	System	03 Oct 2020 10:05:37

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:05:23', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '01546f3c-8fcb-4086-9e6e-a56d7a6e111a' User entered '2'	System	03 Oct 2020 10:05:37
	System	03 Oct 2020 10:05:37

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:05:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '01546f3c-8fcb-4086-9e6e-a56d7a6e111a' User entered 'None (1)'	System	03 Oct 2020 10:05:37
	System	03 Oct 2020 10:05:37

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:05:33', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '01546f3c-8fcb-4086-9e6e-a56d7a6e111a' User entered '03 Oct 2020 06:05'	System	03 Oct 2020 10:05:37
	System	03 Oct 2020 10:05:37

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Oct 2020 14:35'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 2'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
Comment added 'pt reported taking 1000mg of Tylenol one time for injection site being sore'.		19 Oct 2020 15:14:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:43:59', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd7b29b93-0f2f-4ba4-b200-7c6b1be42e0a'	System	03 Oct 2020 20:44:50
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	03 Oct 2020 20:44:50

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:44:23', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd7b29b93-0f2f-4ba4-b200-7c6b1be42e0a' User entered 'Yes (Y)'	System	03 Oct 2020 20:44:50
	System	03 Oct 2020 20:44:50

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:44:18', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd7b29b93-0f2f-4ba4-b200-7c6b1be42e0a' User entered '300'	System	03 Oct 2020 20:44:50
	System	03 Oct 2020 20:44:50

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:44:27', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd7b29b93-0f2f-4ba4-b200-7c6b1be42e0a' User entered 'Yes (Y)'	System	03 Oct 2020 20:44:50
	System	03 Oct 2020 20:44:50

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:44:35', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd7b29b93-0f2f-4ba4-b200-7c6b1be42e0a' User entered '3'	System	03 Oct 2020 20:44:50
	System	03 Oct 2020 20:44:50

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:44:40', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd7b29b93-0f2f-4ba4-b200-7c6b1be42e0a' User entered 'None (1)'	System	03 Oct 2020 20:44:50
	System	03 Oct 2020 20:44:50

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:44:46', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd7b29b93-0f2f-4ba4-b200-7c6b1be42e0a' User entered '03 Oct 2020 16:44'	System	03 Oct 2020 20:44:50
	System	03 Oct 2020 20:44:50

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 3'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:01:04', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'dddf0113-b41d-4aad-b968-f8f1dfa5c12b' User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 10:02:07
	System	05 Oct 2020 10:02:07

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:01:10', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'dddf0113-b41d-4aad-b968-f8f1dfa5c12b' User entered 'Yes (Y)'	System	05 Oct 2020 10:02:07
	System	05 Oct 2020 10:02:07

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:01:24', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'dddf0113-b41d-4aad-b968-f8f1dfa5c12b' User entered '300'	System	05 Oct 2020 10:02:07
	System	05 Oct 2020 10:02:07

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:01:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'dddf0113-b41d-4aad-b968-f8f1dfa5c12b' User entered 'Yes (Y)'	System	05 Oct 2020 10:02:07
	System	05 Oct 2020 10:02:07

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:01:49', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'dddf0113-b41d-4aad-b968-f8f1dfa5c12b' User entered '1'	System	05 Oct 2020 10:02:07
	System	05 Oct 2020 10:02:07

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:01:53', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'dddf0113-b41d-4aad-b968-f8f1dfa5c12b' User entered 'None (1)'	System	05 Oct 2020 10:02:07
	System	05 Oct 2020 10:02:07

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:02:03', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'dddf0113-b41d-4aad-b968-f8f1dfa5c12b' User entered '05 Oct 2020 06:02'	System	05 Oct 2020 10:02:07
	System	05 Oct 2020 10:02:07

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 4'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:53:15', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'ff18949e-f43a-47cc-aa08-8f0708d4b294'	System	05 Oct 2020 22:54:10
User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 22:54:10

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:53:33', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'ff18949e-f43a-47cc-aa08-8f0708d4b294'	System	05 Oct 2020 22:54:10
User entered 'Yes (Y)'	System	05 Oct 2020 22:54:10

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:53:47', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'ff18949e-f43a-47cc-aa08-8f0708d4b294' User entered '1'	System	05 Oct 2020 22:54:10
	System	05 Oct 2020 22:54:10

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:53:57', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'ff18949e-f43a-47cc-aa08-8f0708d4b294'	System	05 Oct 2020 22:54:10
User entered 'No (N)'	System	05 Oct 2020 22:54:10

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'ff18949e-f43a-47cc-aa08-8f0708d4b294'	System	05 Oct 2020 22:54:10
User entered 'None (1)'	System	05 Oct 2020 22:54:10

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:05', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'ff18949e-f43a-47cc-aa08-8f0708d4b294'	System	05 Oct 2020 22:54:10
User entered '05 Oct 2020 18:54'	System	05 Oct 2020 22:54:10

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 5'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:36', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '70a7b4b7-3bcc-4479-906d-cfb589649253'	System	06 Oct 2020 22:50:52
User entered 'None (1)'	System	06 Oct 2020 22:50:52

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:40', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '70a7b4b7-3bcc-4479-906d-cfb589649253' User entered 'No (N)'	System	06 Oct 2020 22:50:52
	System	06 Oct 2020 22:50:52

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:43', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '70a7b4b7-3bcc-4479-906d-cfb589649253' User entered 'No (N)'	System	06 Oct 2020 22:50:52
	System	06 Oct 2020 22:50:52

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:47', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '70a7b4b7-3bcc-4479-906d-cfb589649253' User entered 'None (1)'	System	06 Oct 2020 22:50:52
	System	06 Oct 2020 22:50:52

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:50', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '70a7b4b7-3bcc-4479-906d-cfb589649253' User entered '06 Oct 2020 18:50'	System	06 Oct 2020 22:50:52
	System	06 Oct 2020 22:50:52

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 6'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:09', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6155d40f-73e7-4586-a393-31fc2c0c1af5'	System	07 Oct 2020 22:26:26
User entered 'None (1)'	System	07 Oct 2020 22:26:26

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:12', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6155d40f-73e7-4586-a393-31fc2c0c1af5' User entered 'No (N)'	System	07 Oct 2020 22:26:26
	System	07 Oct 2020 22:26:26

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:15', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6155d40f-73e7-4586-a393-31fc2c0c1af5'	System	07 Oct 2020 22:26:26
User entered 'No (N)'	System	07 Oct 2020 22:26:26

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:19', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6155d40f-73e7-4586-a393-31fc2c0c1af5'	System	07 Oct 2020 22:26:26
User entered 'None (1)'	System	07 Oct 2020 22:26:26

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '6155d40f-73e7-4586-a393-31fc2c0c1af5' User entered '07 Oct 2020 18:26'	System	07 Oct 2020 22:26:26
	System	07 Oct 2020 22:26:26

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 7'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:48:40', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8dfae377-877c-4363-b9d7-6d8810857c98' User entered 'None (1)'	System	08 Oct 2020 23:48:55
	System	08 Oct 2020 23:48:55

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:48:43', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8dfae377-877c-4363-b9d7-6d8810857c98' User entered 'No (N)'	System	08 Oct 2020 23:48:55
	System	08 Oct 2020 23:48:55

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:48:46', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8dfae377-877c-4363-b9d7-6d8810857c98' User entered 'No (N)'	System	08 Oct 2020 23:48:55
	System	08 Oct 2020 23:48:55

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:48:49', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8dfae377-877c-4363-b9d7-6d8810857c98' User entered 'None (1)'	System	08 Oct 2020 23:48:55
	System	08 Oct 2020 23:48:55

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:48:52', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '8dfae377-877c-4363-b9d7-6d8810857c98' User entered '08 Oct 2020 19:48'	System	08 Oct 2020 23:48:55
	System	08 Oct 2020 23:48:55

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:41', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5985993-91d1-4884-a81b-7155d14c9a7a'	System	02 Oct 2020 15:36:07
User entered 'No interference with activity (1)'	System	02 Oct 2020 15:36:07

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:44', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5985993-91d1-4884-a81b-7155d14c9a7a' User entered 'None (0)'	System	02 Oct 2020 15:36:07
	System	02 Oct 2020 15:36:07

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:47', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5985993-91d1-4884-a81b-7155d14c9a7a' User entered 'None (0)'	System	02 Oct 2020 15:36:07
	System	02 Oct 2020 15:36:07

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:49', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5985993-91d1-4884-a81b-7155d14c9a7a' User entered 'None (0)'	System	02 Oct 2020 15:36:07
	System	02 Oct 2020 15:36:07

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:52', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5985993-91d1-4884-a81b-7155d14c9a7a' User entered 'None (0)'	System	02 Oct 2020 15:36:07
	System	02 Oct 2020 15:36:07

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:54', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5985993-91d1-4884-a81b-7155d14c9a7a' User entered 'None (0)'	System	02 Oct 2020 15:36:07
	System	02 Oct 2020 15:36:07

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:35:59', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5985993-91d1-4884-a81b-7155d14c9a7a'	System	02 Oct 2020 15:36:07
User entered 'No (N)'	System	02 Oct 2020 15:36:07

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-02T11:36:03', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5985993-91d1-4884-a81b-7155d14c9a7a'	System	02 Oct 2020 15:36:07
User entered '02 Oct 2020 11:36'	System	02 Oct 2020 15:36:07

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Oct 2020 11:10'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Oct 2020 13:40'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:07:30', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f7eca377-24bd-4718-bb5b-876c56c6f608'	System	03 Oct 2020 10:08:31
User entered 'No interference with activity (1)'	System	03 Oct 2020 10:08:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:07:38', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f7eca377-24bd-4718-bb5b-876c56c6f608'	System	03 Oct 2020 10:08:31
User entered 'Some interference with activity (2)'	System	03 Oct 2020 10:08:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:08:03', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f7eca377-24bd-4718-bb5b-876c56c6f608'	System	03 Oct 2020 10:08:31
User entered 'Some interference with activity (2)'	System	03 Oct 2020 10:08:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:08:07', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f7eca377-24bd-4718-bb5b-876c56c6f608' User entered 'No interference with activity (1)'	System	03 Oct 2020 10:08:31
	System	03 Oct 2020 10:08:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:08:10', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f7eca377-24bd-4718-bb5b-876c56c6f608' User entered 'None (0)'	System	03 Oct 2020 10:08:31
	System	03 Oct 2020 10:08:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:08:12', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f7eca377-24bd-4718-bb5b-876c56c6f608' User entered 'None (0)'	System	03 Oct 2020 10:08:31
	System	03 Oct 2020 10:08:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:08:16', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f7eca377-24bd-4718-bb5b-876c56c6f608' User entered 'No (N)'	System	03 Oct 2020 10:08:31
	System	03 Oct 2020 10:08:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T06:08:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f7eca377-24bd-4718-bb5b-876c56c6f608' User entered '03 Oct 2020 06:08'	System	03 Oct 2020 10:08:31
	System	03 Oct 2020 10:08:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '02 Oct 2020 14:35'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 2'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:44:57', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c42a109c-68bf-47e8-9ec3-dd24d06ff4ac'	System	03 Oct 2020 20:46:28
User entered 'No interference with activity (1)'	System	03 Oct 2020 20:46:28

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:45:13', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c42a109c-68bf-47e8-9ec3-dd24d06ff4ac'	System	03 Oct 2020 20:46:28
User entered 'Significant; prevents daily activity (3)'	System	03 Oct 2020 20:46:28

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:45:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c42a109c-68bf-47e8-9ec3-dd24d06ff4ac' User entered 'Significant; prevents daily activity (3)'	System	03 Oct 2020 20:46:28

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:45:30', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c42a109c-68bf-47e8-9ec3-dd24d06ff4ac'	System	03 Oct 2020 20:46:28
User entered 'Some interference with activity (2)'	System	03 Oct 2020 20:46:28

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:46:07', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c42a109c-68bf-47e8-9ec3-dd24d06ff4ac' User entered 'None (0)'	System	03 Oct 2020 20:46:28
	System	03 Oct 2020 20:46:28

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:46:13', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c42a109c-68bf-47e8-9ec3-dd24d06ff4ac'	System	03 Oct 2020 20:46:28
User entered 'Some interference with activity not requiring medical attention (2)'	System	03 Oct 2020 20:46:28

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:46:23', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c42a109c-68bf-47e8-9ec3-dd24d06ff4ac' User entered 'No (N)'	System	03 Oct 2020 20:46:28
	System	03 Oct 2020 20:46:28

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-03T16:46:26', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c42a109c-68bf-47e8-9ec3-dd24d06ff4ac' User entered '03 Oct 2020 16:46'	System	03 Oct 2020 20:46:28
	System	03 Oct 2020 20:46:28

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 3'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:02:09', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5ed90b6-4cce-4b20-ae62-c727dbdfd023' User entered 'None (0)'	System	05 Oct 2020 10:02:43
	System	05 Oct 2020 10:02:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:02:14', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5ed90b6-4cce-4b20-ae62-c727dbdfd023'	System	05 Oct 2020 10:02:43
User entered 'No interference with activity (1)'	System	05 Oct 2020 10:02:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:02:18', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5ed90b6-4cce-4b20-ae62-c727dbdfd023' User entered 'None (0)'	System	05 Oct 2020 10:02:43
	System	05 Oct 2020 10:02:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:02:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5ed90b6-4cce-4b20-ae62-c727dbdfd023' User entered 'None (0)'	System	05 Oct 2020 10:02:43
	System	05 Oct 2020 10:02:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:02:26', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5ed90b6-4cce-4b20-ae62-c727dbdfd023' User entered 'None (0)'	System	05 Oct 2020 10:02:43
	System	05 Oct 2020 10:02:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:02:30', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5ed90b6-4cce-4b20-ae62-c727dbdfd023' User entered 'None (0)'	System	05 Oct 2020 10:02:43
	System	05 Oct 2020 10:02:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:02:35', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5ed90b6-4cce-4b20-ae62-c727dbdfd023' User entered 'No (N)'	System	05 Oct 2020 10:02:43
	System	05 Oct 2020 10:02:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T06:02:41', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd5ed90b6-4cce-4b20-ae62-c727dbdfd023' User entered '05 Oct 2020 06:02'	System	05 Oct 2020 10:02:43
	System	05 Oct 2020 10:02:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 4'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:11', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'eb75123f-16d0-4bc3-b713-ac407e39eec3' User entered 'None (0)'	System	05 Oct 2020 22:54:43
	System	05 Oct 2020 22:54:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'eb75123f-16d0-4bc3-b713-ac407e39eec3' User entered 'None (0)'	System	05 Oct 2020 22:54:43
	System	05 Oct 2020 22:54:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:24', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'eb75123f-16d0-4bc3-b713-ac407e39eec3' User entered 'None (0)'	System	05 Oct 2020 22:54:43
	System	05 Oct 2020 22:54:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:27', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'eb75123f-16d0-4bc3-b713-ac407e39eec3' User entered 'None (0)'	System	05 Oct 2020 22:54:43
	System	05 Oct 2020 22:54:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:30', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'eb75123f-16d0-4bc3-b713-ac407e39eec3' User entered 'None (0)'	System	05 Oct 2020 22:54:43
	System	05 Oct 2020 22:54:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:33', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'eb75123f-16d0-4bc3-b713-ac407e39eec3' User entered 'None (0)'	System	05 Oct 2020 22:54:43
	System	05 Oct 2020 22:54:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:37', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'eb75123f-16d0-4bc3-b713-ac407e39eec3' User entered 'No (N)'	System	05 Oct 2020 22:54:43
	System	05 Oct 2020 22:54:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-05T18:54:40', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'eb75123f-16d0-4bc3-b713-ac407e39eec3' User entered '05 Oct 2020 18:54'	System	05 Oct 2020 22:54:43
	System	05 Oct 2020 22:54:43

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 5'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:55', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '997c6716-27da-4fda-978f-16cddc2c28f1' User entered 'None (0)'	System	06 Oct 2020 22:51:17
	System	06 Oct 2020 22:51:17

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:50:58', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '997c6716-27da-4fda-978f-16cddc2c28f1' User entered 'None (0)'	System	06 Oct 2020 22:51:17
	System	06 Oct 2020 22:51:17

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:51:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '997c6716-27da-4fda-978f-16cddc2c28f1' User entered 'None (0)'	System	06 Oct 2020 22:51:17
	System	06 Oct 2020 22:51:17

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:51:03', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '997c6716-27da-4fda-978f-16cddc2c28f1' User entered 'None (0)'	System	06 Oct 2020 22:51:17
	System	06 Oct 2020 22:51:17

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:51:05', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '997c6716-27da-4fda-978f-16cddc2c28f1' User entered 'None (0)'	System	06 Oct 2020 22:51:17
	System	06 Oct 2020 22:51:17

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:51:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '997c6716-27da-4fda-978f-16cddc2c28f1' User entered 'None (0)'	System	06 Oct 2020 22:51:17
	System	06 Oct 2020 22:51:17

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:51:12', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '997c6716-27da-4fda-978f-16cddc2c28f1' User entered 'No (N)'	System	06 Oct 2020 22:51:17
	System	06 Oct 2020 22:51:17

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-06T18:51:15', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '997c6716-27da-4fda-978f-16cddc2c28f1' User entered '06 Oct 2020 18:51'	System	06 Oct 2020 22:51:17
	System	06 Oct 2020 22:51:17

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 6'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:27', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a1ada34e-8bca-4bd7-9272-14e1ff9543ff' User entered 'None (0)'	System	07 Oct 2020 22:26:49
	System	07 Oct 2020 22:26:49

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:29', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a1ada34e-8bca-4bd7-9272-14e1ff9543ff' User entered 'None (0)'	System	07 Oct 2020 22:26:49
	System	07 Oct 2020 22:26:49

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:31', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a1ada34e-8bca-4bd7-9272-14e1ff9543ff' User entered 'None (0)'	System	07 Oct 2020 22:26:49
	System	07 Oct 2020 22:26:49

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:33', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a1ada34e-8bca-4bd7-9272-14e1ff9543ff' User entered 'None (0)'	System	07 Oct 2020 22:26:49
	System	07 Oct 2020 22:26:49

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:35', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a1ada34e-8bca-4bd7-9272-14e1ff9543ff' User entered 'None (0)'	System	07 Oct 2020 22:26:49
	System	07 Oct 2020 22:26:49

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:38', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a1ada34e-8bca-4bd7-9272-14e1ff9543ff' User entered 'None (0)'	System	07 Oct 2020 22:26:49
	System	07 Oct 2020 22:26:49

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:41', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a1ada34e-8bca-4bd7-9272-14e1ff9543ff' User entered 'No (N)'	System	07 Oct 2020 22:26:49
	System	07 Oct 2020 22:26:49

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-07T18:26:45', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'a1ada34e-8bca-4bd7-9272-14e1ff9543ff' User entered '07 Oct 2020 18:26'	System	07 Oct 2020 22:26:49
	System	07 Oct 2020 22:26:49

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Oct 2020 15:29:31
User entered 'Day 7'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:48:57', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '554ef2db-7059-4d49-a9b1-2c63b1072d99' User entered 'None (0)'	System	08 Oct 2020 23:49:18
	System	08 Oct 2020 23:49:18

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:49:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '554ef2db-7059-4d49-a9b1-2c63b1072d99' User entered 'None (0)'	System	08 Oct 2020 23:49:18
	System	08 Oct 2020 23:49:18

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:49:03', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '554ef2db-7059-4d49-a9b1-2c63b1072d99' User entered 'None (0)'	System	08 Oct 2020 23:49:18
	System	08 Oct 2020 23:49:18

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:49:05', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '554ef2db-7059-4d49-a9b1-2c63b1072d99' User entered 'None (0)'	System	08 Oct 2020 23:49:18
	System	08 Oct 2020 23:49:18

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:49:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '554ef2db-7059-4d49-a9b1-2c63b1072d99' User entered 'None (0)'	System	08 Oct 2020 23:49:18
	System	08 Oct 2020 23:49:18

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:49:10', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '554ef2db-7059-4d49-a9b1-2c63b1072d99' User entered 'None (0)'	System	08 Oct 2020 23:49:18
	System	08 Oct 2020 23:49:18

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

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 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:49:13', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '554ef2db-7059-4d49-a9b1-2c63b1072d99' User entered 'No (N)'	System	08 Oct 2020 23:49:18
	System	08 Oct 2020 23:49:18

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-10-08T19:49:16', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '554ef2db-7059-4d49-a9b1-2c63b1072d99' User entered '08 Oct 2020 19:49'	System	08 Oct 2020 23:49:18
	System	08 Oct 2020 23:49:18

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 15:29:31

US3222452

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 15:29:31

US3222452

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Albert Garcia (b) (4)	20 Oct 2020 12:59:58

US3222452

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '10 Oct 2020'	Albert Garcia (b) (4)	20 Oct 2020 12:59:58

US3222452

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	20 Oct 2020 12:59:58

US3222452

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Albert Garcia (b) (4)	20 Oct 2020 12:59:58

US3222452

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Albert Garcia (b) (4)	20 Oct 2020 13:00:07

US3222452

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'I'	System	20 Oct 2020 13:00:07

US3222452

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Albert Garcia (b) (4)	20 Oct 2020 13:00:30

US3222452

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '17 Oct 2020'	Albert Garcia (b) (4)	20 Oct 2020 13:00:30

US3222452

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	20 Oct 2020 13:00:30

US3222452

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	20 Oct 2020 13:00:30

US3222452

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Albert Garcia (b) (4)	20 Oct 2020 13:00:40

US3222452

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'I'	System	20 Oct 2020 13:00:40

US3222452

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 01:28:33

US3222452

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
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)	23 Nov 2020 19:19:38
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 'CORRECT AS ENTERED AND NOTED IN SUBJECT CHART' (Site from System).	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:28:47
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	11 Nov 2020 01:28:33
User entered '28 Oct 2020'	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:28:33

US3222452

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	11 Nov 2020 01:28:33

US3222452

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) Albert Garcia (b) (4)	11 Nov 2020 01:28:33

US3222452

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 01:29:08

US3222452

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'I'	System	11 Nov 2020 01:29:08

US3222452

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 01:29:21

US3222452

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '5 Nov 2020'	Albert Garcia (b) (4)	11 Nov 2020 01:29:21

US3222452

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	11 Nov 2020 01:29:21

US3222452

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'VISIT3'	System	11 Nov 2020 01:29:21

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered empty.	System	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered empty.	System	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered empty.	System	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered empty.	System	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered empty.	System	11 Nov 2020 01:29:29

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09

US3222452

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09

US3222452

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'No (N)'	Albert Garcia (b) (4)	11 Nov 2020 01:29:35

US3222452

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered empty.	Albert Garcia (b) (4)	11 Nov 2020 01:29:35

US3222452

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 01:30:04

US3222452

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '5 Nov 2020'	Albert Garcia (b) (4)	11 Nov 2020 01:30:04

US3222452

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered '11:05'	Albert Garcia (b) (4)	11 Nov 2020 01:30:04

US3222452

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered '5 Nov 2020 11:05'	System	11 Nov 2020 01:30:04

US3222452

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:37
User entered 'Yes (Y)'	Albert Garcia (b) (4)	11 Nov 2020 01:30:15

US3222452

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'I'	System	11 Nov 2020 01:30:15

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 64'	System	02 Sep 2020 15:51:30

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-06T11:59:39', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '77f870aa-5e54-41ab-a0ac-402111aa5f73'	System	06 Nov 2020 17:01:20
User entered 'Yes (Y)'	System	06 Nov 2020 17:01:20

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-06T11:59:43', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '77f870aa-5e54-41ab-a0ac-402111aa5f73'	System	06 Nov 2020 17:01:20
User entered 'No (N)'	System	06 Nov 2020 17:01:20

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-06T11:59:51', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '77f870aa-5e54-41ab-a0ac-402111aa5f73'	System	06 Nov 2020 17:01:20
User entered 'No (N)'	System	06 Nov 2020 17:01:20

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-06T12:00:01', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '77f870aa-5e54-41ab-a0ac-402111aa5f73'	System	06 Nov 2020 17:01:20
User entered 'Yes (Y)'	System	06 Nov 2020 17:01:20

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Please 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)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-06T12:00:16', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '77f870aa-5e54-41ab-a0ac-402111aa5f73'	System	06 Nov 2020 17:01:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Nov 2020 17:01:20

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-06T12:00:42', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '77f870aa-5e54-41ab-a0ac-402111aa5f73' User entered '06 Nov 2020 12:00:42'	System	06 Nov 2020 17:01:20
	System	06 Nov 2020 17:01:20

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 15:51:30

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 71'	System	02 Sep 2020 15:51:30

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-12T17:59:26', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '73626b92-0408-4cc6-9c03-08ee2a892ecd' User entered 'No (N)'	System	12 Nov 2020 22:59:48
	System	12 Nov 2020 22:59:48

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-12T17:59:30', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '73626b92-0408-4cc6-9c03-08ee2a892ecd' User entered 'No (N)'	System	12 Nov 2020 22:59:48
	System	12 Nov 2020 22:59:48

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-12T17:59:43', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '73626b92-0408-4cc6-9c03-08ee2a892ecd' User entered '12 Nov 2020 17:59:43'	System	12 Nov 2020 22:59:48
	System	12 Nov 2020 22:59:48

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 15:51:30

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered 'Day 78'	System	02 Sep 2020 15:51:30

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-18T12:00:21', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '3ed51981-1bda-4020-97a8-a5982b1b0e3c'	System	18 Nov 2020 17:00:48
User entered 'No (N)'	System	18 Nov 2020 17:00:48

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-18T12:00:29', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '3ed51981-1bda-4020-97a8-a5982b1b0e3c'	System	18 Nov 2020 17:00:48
User entered 'No (N)'	System	18 Nov 2020 17:00:48

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-18T12:00:38', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '3ed51981-1bda-4020-97a8-a5982b1b0e3c' User entered '18 Nov 2020 12:00:38'	System	18 Nov 2020 17:00:48
	System	18 Nov 2020 17:00:48

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 15:51:30

US3222452

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:55:44
Data entry locked.	System	02 Sep 2020 15:51:30
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 15:51:30

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-30T06:20:28', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '9dec01bd-7e95-41d2-b383-7d065c42bd27'	System	30 Nov 2020 11:20:45
User entered 'No (N)'	System	30 Nov 2020 11:20:45

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-30T06:20:34', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '9dec01bd-7e95-41d2-b383-7d065c42bd27' User entered 'No (N)'	System	30 Nov 2020 11:20:45

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-11-30T06:20:43', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '9dec01bd-7e95-41d2-b383-7d065c42bd27' User entered '30 Nov 2020 06:20:43'	System	30 Nov 2020 11:20:45
	System	30 Nov 2020 11:20:45

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-04T06:17:54', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '9b417c11-2374-416b-8af9-56b67a8eb7fd' User entered 'No (N)'	System	04 Dec 2020 11:18:16
	System	04 Dec 2020 11:18:16

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-04T06:18:07', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '9b417c11-2374-416b-8af9-56b67a8eb7fd' User entered 'No (N)'	System	04 Dec 2020 11:18:16
	System	04 Dec 2020 11:18:16

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-04T06:18:13', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '9b417c11-2374-416b-8af9-56b67a8eb7fd' User entered '04 Dec 2020 06:18:13'	System	04 Dec 2020 11:18:16
	System	04 Dec 2020 11:18:16

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-14T19:01:16', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7bac623e-13ad-4ab7-81df-5722352c1a45'	System	15 Dec 2020 00:01:38
User entered 'No (N)'	System	15 Dec 2020 00:01:38

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-14T19:01:21', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7bac623e-13ad-4ab7-81df-5722352c1a45'	System	15 Dec 2020 00:01:38
User entered 'No (N)'	System	15 Dec 2020 00:01:38

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-14T19:01:32', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7bac623e-13ad-4ab7-81df-5722352c1a45'	System	15 Dec 2020 00:01:38
User entered '14 Dec 2020 19:01:32'	System	15 Dec 2020 00:01:38

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-20T12:43:23', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '27e7bb54-58c6-466f-b3aa-e58c938fea75'	System	20 Dec 2020 17:43:34
User entered 'No (N)'	System	20 Dec 2020 17:43:34

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-20T12:43:27', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '27e7bb54-58c6-466f-b3aa-e58c938fea75'	System	20 Dec 2020 17:43:34
User entered 'No (N)'	System	20 Dec 2020 17:43:34

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-20T12:43:32', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '27e7bb54-58c6-466f-b3aa-e58c938fea75' User entered '20 Dec 2020 12:43:32'	System	20 Dec 2020 17:43:34
	System	20 Dec 2020 17:43:34

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-29T06:25:26', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7dc6f31b-8e0d-452e-bd2d-13db59fd8205' User entered 'No (N)'	System	29 Dec 2020 11:25:38
	System	29 Dec 2020 11:25:38

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-29T06:25:30', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7dc6f31b-8e0d-452e-bd2d-13db59fd8205'	System	29 Dec 2020 11:25:38
User entered 'No (N)'	System	29 Dec 2020 11:25:38

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2020-12-29T06:25:34', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '7dc6f31b-8e0d-452e-bd2d-13db59fd8205' User entered '29 Dec 2020 06:25:34'	System	29 Dec 2020 11:25:38
	System	29 Dec 2020 11:25:38

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-01T05:38:05', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'fb5c941f-591c-4301-bb94-2c7d5a92ba01' User entered 'No (N)'	System	01 Jan 2021 10:38:24
	System	01 Jan 2021 10:38:24

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-01T05:38:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'fb5c941f-591c-4301-bb94-2c7d5a92ba01'	System	01 Jan 2021 10:38:24
User entered 'No (N)'	System	01 Jan 2021 10:38:24

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-01T05:38:22', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'fb5c941f-591c-4301-bb94-2c7d5a92ba01' User entered '01 Jan 2021 05:38:22'	System	01 Jan 2021 10:38:24
	System	01 Jan 2021 10:38:24

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-09T10:57:20', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c12bd157-a3ad-440f-8f39-4fb285b75c48'	System	09 Jan 2021 15:58:09
User entered 'No (N)'	System	09 Jan 2021 15:58:09

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-09T10:57:23', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c12bd157-a3ad-440f-8f39-4fb285b75c48'	System	09 Jan 2021 15:58:09
User entered 'No (N)'	System	09 Jan 2021 15:58:09

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-09T10:57:34', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c12bd157-a3ad-440f-8f39-4fb285b75c48' User entered '09 Jan 2021 10:57:34'	System	09 Jan 2021 15:58:09
	System	09 Jan 2021 15:58:09

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-15T08:00:21', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '2dd6d3b7-122a-4632-9615-0044771e8209' User entered 'No (N)'	System	15 Jan 2021 13:00:31
	System	15 Jan 2021 13:00:31

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-15T08:00:25', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '2dd6d3b7-122a-4632-9615-0044771e8209' User entered 'No (N)'	System	15 Jan 2021 13:00:31
	System	15 Jan 2021 13:00:31

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-15T08:00:29', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '2dd6d3b7-122a-4632-9615-0044771e8209' User entered '15 Jan 2021 08:00:29'	System	15 Jan 2021 13:00:31
	System	15 Jan 2021 13:00:31

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-26T13:20:58', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '090bfc9b-c251-4038-aeb5-29c45d0b9cc8' User entered 'No (N)'	System	26 Jan 2021 19:38:48
	System	26 Jan 2021 19:38:48

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-26T13:21:02', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '090bfc9b-c251-4038-aeb5-29c45d0b9cc8' User entered 'No (N)'	System	26 Jan 2021 19:38:48
	System	26 Jan 2021 19:38:48

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-26T13:21:08', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '090bfc9b-c251-4038-aeb5-29c45d0b9cc8' User entered '26 Jan 2021 13:21:08'	System	26 Jan 2021 19:38:48
	System	26 Jan 2021 19:38:48

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-29T13:51:47', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '015e8407-8d5d-4bcb-9ae0-5c16ee37f2ef' User entered 'No (N)'	System	29 Jan 2021 18:52:01
	System	29 Jan 2021 18:52:01

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-29T13:51:50', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '015e8407-8d5d-4bcb-9ae0-5c16ee37f2ef' User entered 'No (N)'	System	29 Jan 2021 18:52:01

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-01-29T13:51:55', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '015e8407-8d5d-4bcb-9ae0-5c16ee37f2ef' User entered '29 Jan 2021 13:51:55'	System	29 Jan 2021 18:52:01
	System	29 Jan 2021 18:52:01

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-02-07T12:14:01', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '69490e74-3aa4-4128-b2c1-101cb66f534e' User entered 'No (N)'	System	07 Feb 2021 17:14:09
	System	07 Feb 2021 17:14:09

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-02-07T12:14:04', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '69490e74-3aa4-4128-b2c1-101cb66f534e' User entered 'No (N)'	System	07 Feb 2021 17:14:09

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-02-07T12:14:07', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '69490e74-3aa4-4128-b2c1-101cb66f534e' User entered '07 Feb 2021 12:14:07'	System	07 Feb 2021 17:14:09
	System	07 Feb 2021 17:14:09

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-02-14T16:22:44', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'e64713af-603d-489c-868a-731fb15eb2a9' User entered 'No (N)'	System	14 Feb 2021 21:22:52
	System	14 Feb 2021 21:22:52

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-02-14T16:22:46', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'e64713af-603d-489c-868a-731fb15eb2a9' User entered 'No (N)'	System	14 Feb 2021 21:22:52

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-02-14T16:22:50', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'e64713af-603d-489c-868a-731fb15eb2a9' User entered '14 Feb 2021 16:22:50'	System	14 Feb 2021 21:22:52
	System	14 Feb 2021 21:22:52

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-02-23T12:01:41-05:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c32ce2b8-fd95-416d-bd52-fbc95301c1af'	System	23 Feb 2021 18:49:34
User entered 'No (N)'	System	23 Feb 2021 18:49:34

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-02-23T12:01:44-05:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c32ce2b8-fd95-416d-bd52-fbc95301c1af'	System	23 Feb 2021 18:49:34
User entered 'No (N)'	System	23 Feb 2021 18:49:34

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-02-23T12:01:57-05:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'c32ce2b8-fd95-416d-bd52-fbc95301c1af'	System	23 Feb 2021 18:49:34
User entered '23 Feb 2021 17:01:57'	System	23 Feb 2021 18:49:34

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-08T18:08:23-05:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5f857e2e-31ca-4bec-946b-34e9a4ee1332'	System	08 Mar 2021 23:14:55
User entered 'No (N)'	System	08 Mar 2021 23:14:55

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-08T18:08:29-05:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5f857e2e-31ca-4bec-946b-34e9a4ee1332'	System	08 Mar 2021 23:14:55
User entered 'No (N)'	System	08 Mar 2021 23:14:55

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-08T18:08:36-05:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5f857e2e-31ca-4bec-946b-34e9a4ee1332'	System	08 Mar 2021 23:14:55
User entered '08 Mar 2021 23:08:36'	System	08 Mar 2021 23:14:55

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-14T17:23:27-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '2de4f15a-8038-43f6-8348-b51516297f30'	System	14 Mar 2021 21:23:40
User entered 'No (N)'	System	14 Mar 2021 21:23:40

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-14T17:23:32-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '2de4f15a-8038-43f6-8348-b51516297f30'	System	14 Mar 2021 21:23:40
User entered 'No (N)'	System	14 Mar 2021 21:23:40

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-14T17:23:38-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '2de4f15a-8038-43f6-8348-b51516297f30' User entered '14 Mar 2021 21:23:38'	System	14 Mar 2021 21:23:40
	System	14 Mar 2021 21:23:40

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-19T06:00:31-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f4a448e4-fc4a-4ac9-ad97-730c41d2c196'	System	19 Mar 2021 10:00:40
User entered 'No (N)'	System	19 Mar 2021 10:00:40

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-19T06:00:34-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f4a448e4-fc4a-4ac9-ad97-730c41d2c196'	System	19 Mar 2021 10:00:40
User entered 'No (N)'	System	19 Mar 2021 10:00:40

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-19T06:00:38-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f4a448e4-fc4a-4ac9-ad97-730c41d2c196'	System	19 Mar 2021 10:00:40
User entered '19 Mar 2021 10:00:38'	System	19 Mar 2021 10:00:40

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-30T11:59:42-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '69f439a0-c679-4fae-a337-80b05f1eba03'	System	30 Mar 2021 15:59:52
User entered 'No (N)'	System	30 Mar 2021 15:59:52

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-30T11:59:45-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '69f439a0-c679-4fae-a337-80b05f1eba03'	System	30 Mar 2021 15:59:52
User entered 'No (N)'	System	30 Mar 2021 15:59:52

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-30T11:59:50-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '69f439a0-c679-4fae-a337-80b05f1eba03'	System	30 Mar 2021 15:59:52
User entered '30 Mar 2021 15:59:50'	System	30 Mar 2021 15:59:52

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-03T11:40:06-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd6273769-9daf-4d2b-986f-16920a3e5f9c' User entered 'No (N)'	System	03 Apr 2021 15:40:14
	System	03 Apr 2021 15:40:14

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-03T11:40:08-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd6273769-9daf-4d2b-986f-16920a3e5f9c'	System	03 Apr 2021 15:40:14
User entered 'No (N)'	System	03 Apr 2021 15:40:14

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-03T11:40:11-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'd6273769-9daf-4d2b-986f-16920a3e5f9c'	System	03 Apr 2021 15:40:14
User entered '03 Apr 2021 11:40:11'	System	03 Apr 2021 15:40:14

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-09T17:26:14-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5afcb936-f95e-4f4f-8190-6b84278fe9d0'	System	09 Apr 2021 21:26:24
User entered 'No (N)'	System	09 Apr 2021 21:26:24

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-09T17:26:18-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5afcb936-f95e-4f4f-8190-6b84278fe9d0'	System	09 Apr 2021 21:26:24
User entered 'No (N)'	System	09 Apr 2021 21:26:24

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-09T17:26:22-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '5afcb936-f95e-4f4f-8190-6b84278fe9d0'	System	09 Apr 2021 21:26:24
User entered '09 Apr 2021 17:26:22'	System	09 Apr 2021 21:26:24

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-20T06:49:25-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f64c1702-774e-4f18-aa88-a1827fa21952'	System	20 Apr 2021 10:49:41
User entered 'No (N)'	System	20 Apr 2021 10:49:41

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-20T06:49:29-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f64c1702-774e-4f18-aa88-a1827fa21952'	System	20 Apr 2021 10:49:41
User entered 'No (N)'	System	20 Apr 2021 10:49:41

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-20T06:49:36-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'f64c1702-774e-4f18-aa88-a1827fa21952'	System	20 Apr 2021 10:49:41
User entered '20 Apr 2021 06:49:36'	System	20 Apr 2021 10:49:41

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-23T15:33:07-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '206f3046-7258-4a08-927d-cce150c78d3b' User entered 'No (N)'	System	23 Apr 2021 19:33:20
	System	23 Apr 2021 19:33:20

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-23T15:33:13-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '206f3046-7258-4a08-927d-cce150c78d3b' User entered 'No (N)'	System	23 Apr 2021 19:33:20
	System	23 Apr 2021 19:33:20

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-04-23T15:33:17-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '206f3046-7258-4a08-927d-cce150c78d3b' User entered '23 Apr 2021 15:33:17'	System	23 Apr 2021 19:33:20
	System	23 Apr 2021 19:33:20

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-05-01T12:29:05-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'abc9894f-65fe-4abc-b49d-7293d908a1e9' User entered 'No (N)'	System	01 May 2021 16:29:20
	System	01 May 2021 16:29:20

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

Have you been exposed to someone with 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 (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-05-01T12:29:09-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'abc9894f-65fe-4abc-b49d-7293d908a1e9'	System	01 May 2021 16:29:20
User entered 'No (N)'	System	01 May 2021 16:29:20

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-05-01T12:29:16-04:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: 'abc9894f-65fe-4abc-b49d-7293d908a1e9'	System	01 May 2021 16:29:20
User entered '01 May 2021 12:29:16'	System	01 May 2021 16:29:20

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:33:37

US3222452

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:37
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:33:37

US3222452

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:07

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:20:17
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' canceled (Site from DM).		16 Apr 2021 17:31:21
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).		23 Mar 2021 10:19:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-08T18:08:51-05:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '45038204-8bf8-4bc4-913c-e7c906290615'	System	08 Mar 2021 23:15:30
User entered 'Yes (Y)'	System	08 Mar 2021 23:15:30

US3222452

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:07

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:20:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-08T18:09:00-05:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '45038204-8bf8-4bc4-913c-e7c906290615'	System	08 Mar 2021 23:15:30
User entered 'No (N)'	System	08 Mar 2021 23:15:30

US3222452

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:07

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:20:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AC73750-6F04-4DA3-9D66-3E5149C0502D)', Time: '2021-03-08T18:09:06-05:00', User OID: 'PatientReportedOutcome (US3222452)', ODM File OID: '45038204-8bf8-4bc4-913c-e7c906290615' User entered '08 Mar 2021 23:09:06'	System	08 Mar 2021 23:15:30
	System	08 Mar 2021 23:15:30

US3222452

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	heather jackson (b) (4)	31 Dec 2020 17:58:25

US3222452

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	31 Dec 2020 17:58:40
answered by data change (Site from System).		
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	31 Dec 2020 17:58:40
User entered '29 Nov 2020' reason for change: Data Entry Error	heather jackson (b) (4)	31 Dec 2020 17:58:40
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User entered '23 Nov 2020'	System	31 Dec 2020 17:58:25
	heather jackson (b) (4)	31 Dec 2020 17:58:25
	(b) (4)	

US3222452

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	31 Dec 2020 17:58:25

US3222452

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	heather jackson (b) (4)	31 Dec 2020 17:58:25

US3222452

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	heather jackson (b) (4)	31 Dec 2020 17:58:46

US3222452

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:41:09
User entered 'I'	System	31 Dec 2020 17:58:46

US3222452

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	heather jackson (b) (4)	31 Dec 2020 17:58:59

US3222452

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '29 Dec 2020'	heather jackson (b) (4)	31 Dec 2020 17:58:59

US3222452

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	31 Dec 2020 17:58:59

US3222452

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	heather jackson (b) (4)	31 Dec 2020 17:58:59

US3222452

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	heather jackson (b) (4)	31 Dec 2020 17:59:05

US3222452

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User entered 'I'	System	31 Dec 2020 17:59:05

US3222452

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:16:25

US3222452

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:16:25

US3222452

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:16:25

US3222452

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:16:25

US3222452

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:16:28

US3222452

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User entered 'I'	System	27 Jan 2021 18:16:28

US3222452

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:46:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:09:55

US3222452

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:46:39
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:09:55

US3222452

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:46:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:09:55

US3222452

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:46:39
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:09:55

US3222452

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 14:44:35

US3222452

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:25:13
User entered 'I'	System	30 Mar 2021 14:44:35

US3222452

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:50

US3222452

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:50

US3222452

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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 14:35:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:50

US3222452

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	31 Mar 2021 15:49:50

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:49:55

US3222452

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:58

US3222452

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:49:58

US3222452

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:50:06

US3222452

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:50:06

US3222452

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '9:00'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:50:06

US3222452

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 9:00'	System	31 Mar 2021 15:50:06

US3222452

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:50:11

US3222452

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 15:50:11

US3222452

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 13:47:00

US3222452

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:48
	(b) (4)	
User entered '28 Apr 2021'	(b) (4), (b) (6)	28 Apr 2021 13:47:00

US3222452

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 13:47:00

US3222452

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:48
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 13:47:00

US3222452

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 13:47:05

US3222452

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 13:47:05

US3222452

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:37:36

US3222452

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:37:36

US3222452

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Clinic (Clinic)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:37:36

US3222452

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 21:37:36

US3222452

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:37:56

US3222452

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 11:59:21
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:59:25

US3222452

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4)	22 Jan 2021 21:37:56

US3222452

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4)	25 Apr 2021 15:18:05
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 11:59:36
User entered 'Amendment 6 or later (Amendment 6 or later)'		22 Apr 2021 11:59:21
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		22 Apr 2021 07:32:25
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:59:25

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:37:56

US3222452

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4)	22 Jan 2021 21:37:56

US3222452

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4)	22 Jan 2021 21:37:56

US3222452

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:37:56

US3222452

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'No (N)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:37:56

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	22 Jan 2021 21:37:56

US3222452

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:07

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered empty.	System	22 Jan 2021 21:37:56

US3222452

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:38:11

US3222452

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:38:11

US3222452

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '09:40'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:38:11

US3222452

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '22 Jan 2021 09:40'	System	22 Jan 2021 21:38:11

US3222452

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4)	22 Jan 2021 21:38:27

US3222452

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4)	22 Jan 2021 21:38:27

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '09:43'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 21:38:27

US3222452

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:07

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:34:52
User entered '22 Jan 2021 09:43'	System	22 Jan 2021 21:38:27

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:04:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Crystal Paccione (b) (4)	29 Oct 2020 11:42:47
User entered 'No (N)'	(b) (4)	
	Albert Garcia (b) (4)	09 Oct 2020 18:16:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 12:59:51
User entered 'USA-US104-2020-mRNA-1273-P301000014'	System	30 Oct 2020 12:59:24
User entered 'New'	(b) (4), (b) (6)	30 Oct 2020 12:59:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 17:22:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 17:22:34
	(b) (4)	
Data point term sent to Coder	System	06 Nov 2020 17:21:13
Coding entries removed.	douglas winter (b) (4)	06 Nov 2020 17:21:07
	(b) (4)	
User entered 'FALL' reason for change: Data Entry Error	douglas winter (b) (4)	06 Nov 2020 17:21:07
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Cervical vertebral fracture, LLT: Cervical vertebral fracture C3 - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:25:04
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:25:04
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 13:04:29
User entered 'Fracture of cervical vertebrae (C3)'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '26 Oct 2020'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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).	(b) (4)	29 Oct 2020 13:11:54
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Oct 2020 13:11:54
User entered empty; reason for change Data Entry Error	Crystal Paccione (b) (4)	29 Oct 2020 13:11:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Oct 2020 13:03:42
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	29 Oct 2020 13:03:42
User entered 'UK:UK' (non-conformant).	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 13:11:54
User entered '26 Oct 2020 UK:UK' (non-conformant).	System	29 Oct 2020 13:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	13 Nov 2020 13:14:38
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	13 Nov 2020 13:14:38
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	13 Nov 2020 13:13:40
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Please review the stop date of FALL as this is unexpected. Fall is not expected to continue for more than 1 day. Review and update eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the stop date of FALL as this is unexpected. Fall is not expected to continue for more than 1 day. Review and update eCRF as appropriate.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:26:08
User entered '26 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4)	07 Dec 2020 12:43:02
User opened query 'Per DM CLR: Please review the stop date of FALL as this is unexpected. Fall is not expected to continue for more than 1 day. Review and update eCRF as appropriate.' (Site from DM).	(b) (4)	
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).	gail lavine (b) (4)	07 Dec 2020 12:42:41
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)	
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	(b) (4), (b) (6)	03 Dec 2020 12:05:13
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).		16 Nov 2020 21:25:30
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	13 Nov 2020 13:20:46
User entered '30 Oct 2020' reason for change: Data Entry Error	System	13 Nov 2020 13:20:46
	douglas winter (b) (4)	13 Nov 2020 13:14:16
	(b) (4)	
	System	13 Nov 2020 13:13:40
	douglas winter (b) (4)	13 Nov 2020 13:13:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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). User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:06:10
	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	13 Nov 2020 13:19:56
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	13 Nov 2020 13:19:56
User closed query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	13 Nov 2020 13:14:38
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	13 Nov 2020 13:14:38
User opened query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	13 Nov 2020 13:13:40
User entered '13:19' reason for change: Data Entry Error	douglas winter (b) (4)	13 Nov 2020 13:13:40
User entered empty.	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 13:19:56
User entered '30 Oct 2020 13:19'	System	13 Nov 2020 13:13:40
User entered empty.	System	29 Oct 2020 13:03:42

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:43:44
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:02:01
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:00:46
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:23:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:03:42

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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) (b) (4), (b) (6)	24 Nov 2020 12:10:53
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 with 'discharge unknown still admitted' (Site from System).	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:11:24
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	29 Oct 2020 13:03:42
User entered '1'	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:03:42

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '26 Oct 2020'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:43:53
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:02:46
User entered '30 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:02:33
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:23:32
User entered empty.	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4)	06 Nov 2020 15:37:34
	(b) (4)	
User entered '3'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: As the last dose of study drug was given on 02 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:28
Query 'PV Query: As the last dose of study drug was given on 02 Oct 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	06 Nov 2020 15:40:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Nov 2020 15:35:21
User opened query 'PV Query: As the last dose of study drug was given on 02 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:05:52
User entered 'None (NONE)'	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:03:42

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None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	06 Nov 2020 15:41:11
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Oct 2020 13:03:42
User entered '0'	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:03:42

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM: Concomitant Medication check box "checked" however concomitant Medication eCRF has not been updated? Please review and update accordingly or explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:26:23
Query 'Per CDM: Concomitant Medication check box "checked" however concomitant Medication eCRF has not been updated? Please review and update accordingly or explain.' answered with 'updayed' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:34:07
User opened query 'Per CDM: Concomitant Medication check box "checked" however concomitant Medication eCRF has not been updated? Please review and update accordingly or explain.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:27:22
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Nov 2020 15:41:11
User entered '0'	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:03:42

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM: As per your query response "captured in Concomitant Procedures page", Please select the Concomitant Procedure box here and update accordingly, else clarify.' (Site from DM). Query 'Per CDM: As per your query response "captured in Concomitant Procedures page", Please select the Concomitant Procedure box here and update accordingly, else clarify.' answered with 'updated per hospital Dc records and recorded in eCRF' (Site from DM). User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Mar 2021 10:16:44
User opened query 'Per CDM: As per your query response "captured in Concomitant Procedures page", Please select the Concomitant Procedure box here and update accordingly, else clarify.' (Site from DM). User closed query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).		22 Mar 2021 13:25:11
Query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' answered with 'captured in Concomitant Procedures page' (Site from DM).		22 Mar 2021 13:23:47
User opened query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).		12 Mar 2021 11:14:43
User closed query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).		12 Mar 2021 11:14:43
Query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' answered with 'captured in Concomitant Procedures page' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:19:06
User opened query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 16:06:25
User entered '0'	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:03:42

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:25:38
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	13 Nov 2020 13:20:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	13 Nov 2020 13:20:46
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:06:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:03:42

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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)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Crystal Paccione (b) (4)	29 Oct 2020 13:03:42
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the procedure date for the repeat head CT.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:20:30
User closed query 'Per DM CLR: SAE Narrative = REPEAT CT 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).		12 Mar 2021 11:15:14
Query 'Per DM CLR: SAE Narrative = REPEAT CT HEAD. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'captured in Concomitant Procedures page' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:19:26
Query 'PV Query: Please provide the procedure date for the repeat head CT.' answered with 'captured in the Concomitant Procedures page' (Site from Safety).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:19:21
User closed query 'Per DM CLR: SAE Narrative = RESPIRATORY DISTRESS NOTED. Please review and verify if this should be recorded as a separate AE. If yes, please ensure that this medical condition is recorded in the AE eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:47:30
User closed query 'Per DM CLR: SAE Narrative = DAILY PT AND OT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		18 Dec 2020 18:56:21
User closed query 'Per DM CLR: SAE Narrative = PATIENT PLACED IN A C-COLLAR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		18 Dec 2020 18:56:17
User closed query 'Per DM CLR: SAE Narrative = FLEXION-EXTENSION X-RAYS OF THE CERVICAL SPINE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		18 Dec 2020 18:56:08

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = 26/OCT/2020 CT HEAD AND BRAIN. 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)	18 Dec 2020 18:55:47
Query 'Per DM CLR: SAE Narrative = RESPIRATORY DISTRESS NOTED. Please review and verify if this should be recorded as a separate AE. If yes, please ensure that this medical condition is recorded in the AE eCRF as appropriate. Otherwise, clarify.' answered with 'please let us know where respiratory distress was noted. CXR results minimal atelectasis but no SOB or distress noted' (Site from DM).	gail lavine (b) (4) (b) (4)	07 Dec 2020 13:50:11
Query 'Per DM CLR: SAE Narrative = DAILY PT AND OT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added to con procedures' (Site from DM).	gail lavine (b) (4) (b) (4)	07 Dec 2020 13:24:20
Query 'Per DM CLR: SAE Narrative = PATIENT PLACED IN A C-COLLAR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added to con procedures' (Site from DM).	gail lavine (b) (4) (b) (4)	07 Dec 2020 13:24:11
Query 'Per DM CLR: SAE Narrative = FLEXION-EXTENSION X-RAYS OF THE CERVICAL SPINE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added to con procedures' (Site from DM).	gail lavine (b) (4) (b) (4)	07 Dec 2020 13:23:56
Query 'Per DM CLR: SAE Narrative = 26/OCT/2020 CT HEAD AND BRAIN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'corrected' (Site from DM).	gail lavine (b) (4) (b) (4)	07 Dec 2020 13:03:15
User closed query 'PV Query: Please provide the results for 'CT Maxillofacial' performed on 26 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 17:43:16

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = DAILY PT AND OT. 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 12:08:21
User opened query 'Per DM CLR: SAE Narrative = PATIENT PLACED IN A C-COLLAR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		03 Dec 2020 12:08:14
User opened query 'Per DM CLR: SAE Narrative = FLEXION-EXTENSION X-RAYS OF THE CERVICAL SPINE. However, this is not recorded in the ConProc eCRF. Please review and ensure that thi is captured in the appropriate eCRF. ' (Site from DM).		03 Dec 2020 12:08:09
User opened query 'Per DM CLR: SAE Narrative = RESPIRATORY DISTRESS NOTED. Please review and verify if this should be recorded as a separate AE. If yes, please ensure that this medical condition is recorded in the AE eCRF as appropriate. Otherwise, clarify.' (Site from DM).		03 Dec 2020 12:08:03
User opened query 'Per DM CLR: SAE Narrative = REPEAT CT 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).		03 Dec 2020 12:07:57
User opened query 'Per DM CLR: SAE Narrative = 26/OCT/2020 CT HEAD AND BRAIN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		03 Dec 2020 12:07:45
Query 'PV Query: Please provide the results for 'CT Maxillofacial' performed on 26 Oct 2020.' answered with '10/26/2020 CT maxillofacial-Accure displaced right nasal bone fracture' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 17:01:02

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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:25:49
User opened query 'PV Query: Please provide the procedure date for the repeat head CT.' (Site from Safety).		16 Nov 2020 20:06:16
User opened query 'PV Query: Please provide the results for 'CT Maxillofacial' performed on 26 Oct 2020.' (Site from Safety).		16 Nov 2020 20:05:46
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4) (b) (4)	13 Nov 2020 13:38:00

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[Narrative](#)

Audit	User	Time (GMT)
User entered "THE PATIENT WAS CALLED FOR A DAY 50 SAFETY CALL AND SHE REPORTED SHE FELL AT HOME ON 10/26/20 AND WAS ADMITTED TO THE ICU. SHE STATES SHE FRACTURED HER C3 AND HAS A HEMATOMA AND IS STILL IN ICU. SHE STATES SHE WOULD LIKE TO CONTINUE THE STUDY. WILL SEND FOR MEDICAL RECORDS TODAY FOR FURTHER INFORMATION. ADMISSION NOTES: PATIENT WAS TRANSPORTED BY AMBULANCE AFTER LOSING HER FOOTING FROM A STANDING POSITION AT HOME, 8/10 NECK PAIN AND LACERATION TO BACK OF HEAD AND FOREHEAD. EMERGENCY DEPARTMENT PROCEDURES: 26/OCT/2020 CT MAXILLOFACIAL, CT SPINE CERVICAL, CT HEAD AND BRAIN. CT SCAN OF THE BRAIN AND C-SPINE AND WAS NOTED TO HAVE A TEAR DROP C3 FRACTURES AS WELL AS A SMALL SUBDURAL LEFT PARAFALACINE SUBDURAL HEMATOMA. AND THE CT RULED OUT VESEL INJURIES. NEUROSURGERY WAS CONSULTED "RECCOMENDED NO SURGINCAL INTERVENTION" PATIENT PLACED IN A C-COLLAR. SHE IS ABLE TO MOVE ALL EXTREMITIES, NO FOCAL DEFICITES NOTED. REPEAT CT HEAD SHOWED WORSENING OF HEMATOMA. BLOOD PRESSURE REMAINS STABLE NO SEIZURE PROPHYLAXIS PER NEUROSURGERY. PATIENT NOW STABLE FOR DOWNGRADE OUT OF THE ICU. CASE WAS DISCUSSED WITH CRITICAL CARE INTENSIVIST. DIAGNOSIS: SUBDURAL HEMATOMA C3 CERVIACL FRACTURE FACIAL LACERATION NASAL FRACTURE ADVANCED AGE ADMITTED TO ICU ON 26/OCT/2020 @ 23:48 AND DOWNGRADED FROM THE ICU ON 27/OCT/2020 @ 14:11. DISCHARGE	douglas winter (b) (4)	13 Nov 2020 13:37:37

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[Narrative](#)

Audit	User	Time (GMT)
SUMMARY: DENIES ANY SHORTNESS OF BREATH. NO FOCAL DEFICITS NOTED ON EXAM. ALERT AND ORIENTED. SHE IS HEMODYNAMICALLY STABLE. SINUS BRADYCARDIA HEART RATE 54. RESPIRATORY DISTRESS NOTED. SHE DOES HAVE PAIN TO FACE SECONDARY TO NOSE FRACTURE AND GENERALIZED PAIN FROM FALL. FLEXION-EXTENSION X-RAYS OF THE CERVICAL SPINE WITHOUT INSTABILITY. CONTINUE MIAMI J COLLAR. DAILY PT AND OT. BLOOD PRESSURE REMAINED CONTROLLED. NO FOCAL DEFICITS. PATIENT WAS CLEARED BY NEUROSURGERY FOR DISCHARGE. DISCHARGED HOME WITH HOME HEALTH CARE.' reason for change: Data Entry Error		

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[Narrative](#)

Audit	User	Time (GMT)
User entered "THE PATIENT WAS CALLED FOR A DAY 50 SAFETY CALL AND SHE REPORTED SHE FELL AT HOME ON 10/26/20 AND WAS ADMITTED TO THE ICU. SHE STATES SHE FRACTURED HER C3 AND HAS A HEMATOMA AND IS STILL IN ICU. SHE STATES SHE WOULD LIKE TO CONTINUE THE STUDY. WILL SEND FOR MEDICAL RECORDS TODAY FOR FURTHER INFORMATION. ADMISSION NOTES: PATIENT WAS TRANSPORTED BY AMBULANCE AFTER LOSING HER FOOTING FROM A STANDING POSITION AT HOME, 8/10 NECK PAIN AND LACERATION TO BACK OF HEAD AND FOREHEAD. EMERGENCY DEPARTMENT PROCEDURES: 26/OCT/2020 CT MAXILLOFACIAL, CT SPINE CERVICAL, CT HEAD AND BRAIN. CT SCAN OF THE BRAIN AND C-SPINE AND WAS NOTED TO HAVE A TEAR DROP C3 FRACTURES AS WELL AS A SMALL SUBDURAL LEFT PARAFALACINE SUBDURAL HEMATOMA. AND THE CT RULED OUT VESEL INJURIES. NEUROSURGERY WAS CONSULTED "RECCOMENDED NO SURGINCAL INTERVENTION" PATIENT PLACED IN A C-COLLAR. SHE IS ABLE TO MOVE ALL EXTREMITIES, NO FOCAL DEFICITES NOTED. REPEAT CT HEAD SHOWED WORSENING OF HEMATOMA. BLOOD PRESSURE REMAINS STABLE NO SEIZURE PROPHYLAXIS PER NEUROSURGERY. PATIENT NOW STABLE FOR DOWNGRADE OUT OF THE ICU. CASE WAS DISCUSSED WITH CRITICAL CARE INTENSIVIST. DIAGNOSIS: SUBDURAL HEMATOMA C3 CERVIACL FRACTURE FACIAL LACERATION NASAL FRACTURE ADVANCED AGE ADMITTED TO ICU ON 26/OCT/2020 @ 23:48 AND DOWNGRADED FROM THE ICU ON 27/OCT/2020 @ 14:11. DISCHARGE	douglas winter (b) (4)	13 Nov 2020 13:36:51

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[Narrative](#)

Audit	User	Time (GMT)
SUMMARY: DENIES ANY SHORTNESS OF BREATH. NO FOCAL DEFICITS NOTED ON EXAM. ALERT AND ORIENTED. SHE IS HEMODYNAMICALLY STABLE. SINUS BRADYCARDIA HEART RATE 54. RESPIRATORY DISTRESS NOTED. SHE DOES HAVE PAIN TO FACE SECONDARY TO NOSE FRACTURE AND GENERALIZED PAIN FROM FALL. FLEXION-EXTENSION X-RAYS OF THE CERVICAL SPINE WITHOUT INSTABILITY. CONTINUE MIAMI J COLLAR. DAILY PT AND OT. BLOOD PRESSURE REMAINED CONTROLLED. NO FOCAL DEFICITS. PATIENT WAS CLEARED BY NEUROSURGERY FOR DISCHARGE.'		
change: Data Entry Error		
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 13:11:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		09 Nov 2020 13:11:39
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).		09 Nov 2020 13:11:37
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 TEST NOT DONE, AND YET, I'M STILL WAITING ON ADDITIONAL RECORDS FROM THIS INCIDENT.' (Site from Safety).	douglas winter (b) (4) (b) (4)	07 Nov 2020 16:17:29

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Folder: Adverse Events

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Audit	User	Time (GMT)
User entered "THE PATIENT WAS CALLED FOR A DAY 50 SAFETY CALL AND SHE REPORTED SHE FELL AT HOME ON 10/26/20 AND WAS ADMITTED TO THE ICU. SHE STATES SHE FRACTURED HER C3 AND HAS A HEMATOMA AND IS STILL IN ICU. SHE STATES SHE WOULD LIKE TO CONTINUE THE STUDY. WILL SEND FOR MEDICAL RECORDS TODAY FOR FURTHER INFORMATION. ADMISSION NOTES: PATIENT WAS TRANSPORTED BY AMBULANCE AFTER LOSING HER FOOTING FROM A STANDING POSITION AT HOME, 8/10 NECK PAIN AND LACERATION TO BACK OF HEAD AND FOREHEAD. EMERGENCY DEPARTMENT PROCEDURES: 26/OCT/2020 CT MAXILLOFACIAL, CT SPINE CERVICAL, CT HEAD AND BRAIN. CT SCAN OF THE BRAIN AND C-SPINE AND WAS NOTED TO HAVE A TEAR DROP C3 FRACTURES AS WELL AS A SMALL SUBDURAL LEFT PARAFALACINE SUBDURAL HEMATOMA. AND THE CT RULED OUT VESEL INJURIES. NEUROSURGERY WAS CONSULTED "RECCOMENDED NO SURGINCAL INTERVENTION" PATIENT PLACED IN A C-COLLAR. SHE IS ABLE TO MOVE ALL EXTREMITIES, NO FOCAL DEFICITES NOTED. REPEAT CT HEAD SHOWED WORSENING OF HEMATOMA. BLOOD PRESSURE REMAINS STABLE NO SEIZURE PROPHYLAXIS PER NEUROSURGERY. PATIENT NOW STABLE FOR DOWNGRADE OUT OF THE ICU. CASE WAS DISCUSSED WITH CRITICAL CARE INTENSIVIST. THE NEUROSURGEON WAS CONSULTED AND PATIENT WAS ADMITTED TO THE ICU ON 26/OCT/2020. AND DISCHARGED ON 27/OCT/2020 AFTER CONSULTING DIAGNOSIS: SUBDURAL HEMATOMA C3 CERVIACL FRACTURE FACIAL LACERATION<br	douglas winter (b) (4) (b) (4)	07 Nov 2020 16:16:27

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Audit	User	Time (GMT)
/ > NASAL FRACTURE < br / > ADVANCED AGE < br / > ADMITTED TO ICU ON 26 / OCT / 2020 @ 23 : 48 AND DOWNGRADED FROM THE ICU ON 27 / OCT / 2020 @ 14 : 11 . ' reason for change: Data Entry Error		
User entered 'THE PATIENT WAS CALLED FOR A DAY 50 SAFETY CALL AND SHE REPORTED SHE FELL AT HOME ON 10/26/20 AND WAS ADMITTED TO THE ICU. SHE STATES SHE FRACTURED HER C3 AND HAS A HEMATOMA AND IS STILL IN ICU. SHE STATES SHE WOULD LIKE TO CONTINUE THE STUDY. WILL SEND FOR MEDICAL RECORDS TODAY FOR FURTHER INFORMATION. ADMISSION NOTES: PATIENT WAS TRANSPORTED BY AMBULANCE AFTER LOSING HER FOOTING FROM A STANDING POSITION AT HOME, 8/10 NECK PAIN AND LACERATION TO BACK OF HEAD AND FOREHEAD. EMERGENCY DEPARTMENT PROCEDURES: 26/OCT/2020 CT MAXILLOFACIAL, CT SPINE CERVICAL, CT HEAD AND BRAIN. CT SCAN OF THE BRAIN AND C-SPINE AND WAS NOTED TO HAVE A TEAR DROP C3 FRACTURES AS WELL AS A SMALL SUBDURAL LEFT PARAFALACINE SUBDURAL HEMATOMA. AND THE CT RULED OUT VESEL INJURIES. THE NEUROSURGEON WAS CONSULTED AND PATIENT WAS ADMITTED TO THE ICU. DIAGNOSIS: SUBDURAL HEMATOMA C3 CERVIACL FRACTURE FACIAL LACERATION NASAL FRACTURE ADVANCED AGE ADMITTED TO ICU ON 26/OCT/2020 @ 23:48 AND DOWNGRADED FROM THE ICU ON 27/OCT/2020 @ 14:11.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Nov 2020 16:06:55

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE PATIENT WAS CALLED FOR A DAY 50 SAFETY CALL AND SHE REPORTED SHE FELL AT HOME ON 10/26/20 AND WAS ADMITTED TO THE ICU. SHE STATES SHE FRACTURED HER C3 AND HAS A HEMATOMA AND IS STILL IN ICU. SHE STATES SHE WOULD LIKE TO CONTINUE THE STUDY. WILL SEND FOR MEDICAL RECORDS TODAY FOR FURTHER INFORMATION. ADMISSION NOTES: PATIENT WAS TRANSPORTED BY AMBULANCE AFTER LOSING HER FOOTING FROM A STANDING POSITION AT HOME, 8/10 NECK PAIN AND LACERATION TO BACK OF HEAD AND FOREHEAD. EMERGENCY DEPARTMENT PROCEDURES: 26/OCT/2020 CT MAXILLOFACIAL, CT SPINE CERVICAL, CT HEAD AND BRAIN. CT SCAN OF THE BRAIN AND C-SPINE AND WAS NOTED TO HAVE C3 FRACTURES AS WELL AS A SMALL SUBDURAL LEFT PARAFALACINE SUBDURAL HEMATOMA. AND THE CT RULED OUT VESEL INJURIES. THE NEUROSURGEON WAS CONSULTED AND PATIENT WAS ADMITTED TO THE ICU. DIAGNOSIS: SUBDURAL HEMATOMA C3 CERVIACL FRACTURE FACIAL LACERATION NASAL FRACTURE ADVANCED AGE ADMITTED TO ICU ON 26/OCT/2020 @ 23:48 AND DOWNGRADED FROM THE ICU ON 27/OCT/2020 @ 14:11.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Nov 2020 15:56:07
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'ADDED TO NARATIVE' (Site from Safety).	douglas winter (b) (4) (b) (4)	06 Nov 2020 15:43:04
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' answered with 'LOST HER FOOTING ' (Site from Safety).	douglas winter (b) (4) (b) (4)	06 Nov 2020 15:42:13

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE PATIENT WAS CALLED FOR A DAY 50 SAFETY CALL AND SHE REPORTED SHE FELL AT HOME ON 10/26/20 AND WAS ADMITTED TO THE ICU. SHE STATES SHE FRACTURED HER C3 AND HAS A HEMATOMA AND IS STILL IN ICU. SHE STATES SHE WOULD LIKE TO CONTINUE THE STUDY. WILL SEND FOR MEDICAL RECORDS TODAY FOR FURTHER INFORMATION. ADMISSION NOTES: PATIENT WAS TRANSPORTED BY AMBULANCE AFTER LOSING HER FOOTING FROM A STANDING POSITION AT HOME, 8/10 NECK PAIN AND LACERATION TO BACK OF HEAD AND FOREHEAD. EMERGENCY DEPARTMENT PROCEDURES: 26/OCT/2020 CT MAXILLOFACIAL, CT SPINE CERVICAL, CT HEAD AND BRAIN. CT SCAN OF THE BRAIN AND C-SPINE AND WAS NOTED TO HAVE C3 FRACTURES AS WELL AS A SMALL SUBDURAL HEMORRHAGE, AND THE CT RULED OUT VESEL INJURIES. THE NEUROSURGEON WAS CONSULTED AND PATIENT WAS ADMITTED TO THE ICU. DIAGNOSIS: SUBDURAL HEMATOMA C3 CERVICAL FRACTURE FACIAL LACERATION NASAL FRACTURE ADVANCED AGE ADMITTED TO ICU ON 26/OCT/2020 @ 23:48 AND DOWNGRADED FROM THE ICU ON 27/OCT/2020 @ 14:11.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Nov 2020 15:39:37

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE PATIENT WAS CALLED FOR A DAY 50 SAFETY CALL AND SHE REPORTED SHE FELL AT HOME ON 10/26/20 AND WAS ADMITTED TO THE ICU. SHE STATES SHE FRACTURED HER C3 AND HAS A HEMATOMA AND IS STILL IN ICU. SHE STATES SHE WOULD LIKE TO CONTINUE THE STUDY. WILL SEND FOR MEDICAL RECORDS TODAY FOR FURTHER INFORMATION. ADMISSION NOTES: PATIENT WAS TRANSPORTED BY AMBULANCE AFTER LOSING HER FOOTING FROM A STANDING POSITION AT HOME, 8/10 NECK PAIN AND LACERATION TO BACK OF HEAD AND FOREHEAD. EMERGENCY DEPARTMENT PROCEDURES: 26/OCT/2020 CT MAXILLOFACIAL, CT SPINE CERVICAL, CT HEAD AND BRAIN. CT SCAN OF THE BRAIN AND C-SPINE AND WAS NOTED TO HAVE C3 FRACTURES AS WELL AS A SMALL SUBDURAL HEMORRHAGE, AND THE CT RULED OUT VESEL INJURIES. THE NEUROSURGEON WAS CONSULTED AND PATIENT WAS ADMITTED TO THE ICU. DIAGNOSIS: SUBDURAL HEMATOMA C3 CERVICAL FRACTURE FACIAL LACERATION NASAL FRACTURE ADVANCED AGE ADMITTED TO ICU ON 26/OCT/2020 @ 23:48'	douglas winter (b) (4) (b) (4)	06 Nov 2020 15:25:18
reason for change: Data Entry Error User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:07:14

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 15:06:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		06 Nov 2020 15:06:32
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).		06 Nov 2020 15:06:22
User entered 'The patient was called for a day 50 safety call and she reported she fell at home on 10/26/20 and was admitted to the ICU. She states she fractured her C3 and has a hematoma and is still in ICU. She states she would like to continue the study. Will send for medical records today for further information. As of today no information on procedures or medication.'	Crystal Paccione (b) (4) (b) (4)	29 Oct 2020 13:03:42

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 13:03:42

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 13:03:42

US3222452

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 13:03:42

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 02:10:20
User entered	(b) (4), (b) (6)	12 Nov 2020 02:09:11
'USA-US104-2020-mRNA-1273-P301000014'		

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Subdural haematoma, LLT: Subdural hematoma - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 17:20:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 17:20:24
	(b) (4)	
Data point term sent to Coder	System	06 Nov 2020 17:20:12
User entered 'SUBDURAL HEMATOMA'	douglas winter (b) (4)	06 Nov 2020 17:20:07
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '26 Oct 2020'	douglas winter (b) (4)	06 Nov 2020 17:20:07
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 15:48:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 15:48:16
User entered 'No (N)' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 15:48:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 15:47:55
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 15:47:55
User entered empty; reason for change Data Entry Error	gail lavine (b) (4)	02 Dec 2020 15:47:55
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 15:47:05
User entered 'Yes (Y)'	douglas winter (b) (4)	06 Nov 2020 17:20:07
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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) (4), (b) (6)	03 Dec 2020 17:44:29
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).	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:51:51
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 15:47:37
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Dec 2020 15:47:37
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	02 Dec 2020 15:47:05
User entered '30 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:47:05
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)	16 Nov 2020 20:07:04
User entered empty.	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:27
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated per PI' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:50:20
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:53:57
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:22:03
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	11 Nov 2020 01:48:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 01:48:02
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	06 Nov 2020 17:20:07
User entered 'No (N)'	douglas winter (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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) (b) (4), (b) (6)	24 Nov 2020 15:18:21
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 with 'USA-US104-2020-MRNA-1273-P301000014' (Site from System).	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:21:41
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	06 Nov 2020 17:20:07
User entered 'I'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '26 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:00
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:50:24
User entered '30 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:47:05
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:21:40
User entered empty.	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '1'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:26:47
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'updated' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:57:30
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:57:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:54:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:51:32
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:12:08
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '1'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM: As per your query response "captured in Concomitant Procedures page", Please select the Concomitant Procedure check box here and update accordingly, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 10:18:11
Query 'Per CDM: As per your query response "captured in Concomitant Procedures page", Please select the Concomitant Procedure check box here and update accordingly, else clarify.' answered with 'Updated per hospital Dc records and documented in eCRF' (Site from DM).		22 Mar 2021 13:26:15
User entered '1' reason for change: Data Entry Error		22 Mar 2021 13:26:08
User opened query 'Per CDM: As per your query response "captured in Concomitant Procedures page", Please select the Concomitant Procedure check box here and update accordingly, else clarify.' (Site from DM).		12 Mar 2021 11:16:16
User closed query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).		12 Mar 2021 11:16:16
Query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' answered with 'captured in Concomitant Procedures page' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:19:44
User opened query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 16:07:08
User entered '0'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:44:39
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:55:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 15:47:37
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:07:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'THE SAE WAS THE MECHANISM OF INJURY AND THIS SUBDURAL HEMATOMA WAS DIAGNOSED FROM A CT OF THE BRAIN.'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 01:48:02
User entered '0'	System	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 17:20:07

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 02:10:03
User entered 'USA-US104-2020-mRNA-1273-P301000014'		12 Nov 2020 02:09:58

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Cervical vertebral fracture, LLT: Cervical vertebral fracture C3 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	07 Nov 2020 07:56:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Nov 2020 07:56:28
Data point term sent to Coder	System	06 Nov 2020 22:04:14
User entered 'C3 CERVICAL FRACTURE'	douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '26 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 16:51:52
User entered 'No (N)' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 16:51:52
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 16:51:30
User entered 'Yes (Y)'	douglas winter (b) (4)	06 Nov 2020 22:03:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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) (4), (b) (6)	03 Dec 2020 17:45:58
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).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:54:09
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 16:53:41
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Dec 2020 16:53:41
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	02 Dec 2020 16:51:30
User entered '30 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:51:30
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)	16 Nov 2020 20:08:27
User entered empty.	douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4)	
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 17:46:29
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 16:54:11
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 16:51:30
User entered 'Grade 4 (Grade 4)'	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 20:20:01
	douglas winter (b) (4)	06 Nov 2020 22:03:59
	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 22:03:30
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	11 Nov 2020 01:48:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 01:48:41
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	11 Nov 2020 01:48:26
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	06 Nov 2020 22:03:59
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	06 Nov 2020 22:03:59
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	06 Nov 2020 22:03:30
User entered 'No (N)'	douglas winter (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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) (b) (4), (b) (6)	23 Nov 2020 21:27:06
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 with 'UPDATED' (Site from System).	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:48:49
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		11 Nov 2020 01:48:26
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	11 Nov 2020 01:48:26
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	11 Nov 2020 01:48:26
User entered '1' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	11 Nov 2020 01:48:26
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	06 Nov 2020 22:03:30
User entered '0'	douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '26 Oct 2020'	douglas winter (b) (4)	06 Nov 2020 22:03:30
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:38
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:54:25
User entered '30 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:51:30
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:20:28
User entered empty.	douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:27:17
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered with 'SHE WAS IN THE ICU SINCE THIS IS NOT THE SAE BUT THE AE.' (Site from System).	douglas winter (b) (4) (b) (4)	06 Nov 2020 22:10:18
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	06 Nov 2020 22:03:30
User entered 'I'	douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'I'	douglas winter (b) (4)	06 Nov 2020 22:03:30
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM: As per your query response "captured in Concomitant Procedures page", Please select the Concomitant Procedure check box here and update accordingly, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:15:37
Query 'Per CDM: As per your query response "captured in Concomitant Procedures page", Please select the Concomitant Procedure check box here and update accordingly, else clarify.' answered with 'Updated per hospital Dc records and documented in eCRF' (Site from DM).		22 Mar 2021 13:27:08
User entered '1' reason for change: Data Entry Error		22 Mar 2021 13:27:00
User opened query 'Per CDM: As per your query response "captured in Concomitant Procedures page", Please select the Concomitant Procedure check box here and update accordingly, else clarify.' (Site from DM).		12 Mar 2021 11:17:08
User closed query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).		12 Mar 2021 11:17:08
Query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' answered with 'captured in Concomitant Procedures page' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:19:56
User opened query 'Per DM CLR: Please review if Concomitant Procedures were also done for this AE as there are procedures recorded that matches the indication and timeframe of this AE condition. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 16:08:09
User entered '0'	douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:09
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:54:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:53:41
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:09:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'PLEASE REFER TO THE FALL AS HER SAE AND THIS C3 CERVICAL FRACTURE WAS A RESULT OF THAT FALL.'	(b) (4) douglas winter (b) (4)	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 01:48:41
User entered '0'	System	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 22:03:30

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 02:11:09
User entered 'USA-US104-2020-mRNA-1273-P301000014'		12 Nov 2020 02:11:03

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration of face - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Nov 2020 11:12:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:12:29
Data point term sent to Coder	System	07 Nov 2020 15:45:09
User entered 'FACIAL LACERATION'	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '26 Oct 2020'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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).	(b) (4)	07 Nov 2020 15:48:11
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	07 Nov 2020 15:48:11
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	07 Nov 2020 15:44:45
User entered '23:30'	douglas winter (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 15:48:11
User entered '26 Oct 2020 23:30'	System	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 16:56:54
User entered 'No (N)' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 16:56:54
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 16:55:47
User entered 'Yes (Y)'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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) (4), (b) (6)	03 Dec 2020 17:47:15
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).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:56:01
User entered '30 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:55:47
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)	16 Nov 2020 20:10:05
User entered empty.	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:47:43
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:56:35
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:55:47
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:19:06
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	11 Nov 2020 01:49:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 01:49:05
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	07 Nov 2020 15:48:11
User entered 'No (N)'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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) (b) (4), (b) (6)	24 Nov 2020 15:18:59
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 with 'UPDATED' (Site from System).	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:48:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		07 Nov 2020 15:48:11
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	07 Nov 2020 15:48:11
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	07 Nov 2020 15:48:11
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:48:11
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Nov 2020 15:44:45
User entered '0'	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '26 Oct 2020'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:47:37
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:57:03
User entered '30 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:55:47
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:18:48
User entered empty.	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System (b) (4)	07 Nov 2020 15:48:11
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	07 Nov 2020 15:48:11
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	07 Nov 2020 15:44:45
User entered 'I'	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:47:22
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:57:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:55:47
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:10:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'REFER TO PRIMARY SAE: USA-US104-2020-MRNA-1273-P301000014. FACIAL LACERATION IS SECONDARY TO THE PRIMARY SAE WHICH IS THE FALL.' reason for change: Data Entry Error	douglas winter (b) (4)	07 Nov 2020 15:47:20
	(b) (4)	
User entered empty.	douglas winter (b) (4)	07 Nov 2020 15:44:45
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 01:49:05
User entered '0'	System	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Nov 2020 15:44:45

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:08
User entered 'USA-US104-2020-mRNA-1273-P301000014'		12 Nov 2020 20:08:01

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Fractured nose - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	07 Nov 2020 15:56:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Nov 2020 15:56:33
Data point term sent to Coder	System	07 Nov 2020 15:55:11
User entered 'NASAL FRACTURE'	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '26 Oct 2020'	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 16:08:51
User entered 'No (N)' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 16:08:51
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 16:08:26
User entered 'Yes (Y)'	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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) (4), (b) (6)	03 Dec 2020 17:48:30
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 16:10:13
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Dec 2020 16:10:13
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).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:09:20
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 16:08:26
User entered '30 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:08:26
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)	16 Nov 2020 20:11:31
User entered empty.	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 17:48:45
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety).	gail lavine (b) (4)	02 Dec 2020 16:57:57
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 16:57:49
	(b) (4)	
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:17:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	11 Nov 2020 01:49:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4)	11 Nov 2020 01:49:24
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	07 Nov 2020 15:55:05
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Nov 2020 15:54:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Nov 2020 15:54:46
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	07 Nov 2020 15:54:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	07 Nov 2020 15:54:33
User entered empty.	System	07 Nov 2020 15:54:33
	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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) (b) (4), (b) (6)	24 Nov 2020 15:19:15
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 with 'IT WAS ADDED?' (Site from System).	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:55:42
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		07 Nov 2020 15:55:05
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	07 Nov 2020 15:55:05
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	07 Nov 2020 15:55:05
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:55:05
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Nov 2020 15:54:33
User entered '0'	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '26 Oct 2020'	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:48:54
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:11:10
User entered '30 Oct 2020' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:10:13
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:18:11
User entered empty.	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System (b) (4)	07 Nov 2020 15:55:05
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	07 Nov 2020 15:55:05
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	07 Nov 2020 15:54:33
User entered 'I'	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1'	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	douglas winter (b) (4)	07 Nov 2020 15:54:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:48:37
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:10:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:10:13
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:11:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

US3222452

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'PRIMARY SAE: USA-US104-2020-MRNA-1273-P301000014. NASAL FRACTURE IS SECONDARY TO THE PRIMARY SAE "FALL".'	(b) (4) douglas winter (b) (4) (b) (4)	07 Nov 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 01:49:24
User entered '0'	System	07 Nov 2020 15:54:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	07 Nov 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Nov 2020 15:54:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 13:08:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 13:08:51
	(b) (4)	
Data point term sent to Coder	System	22 Mar 2021 13:07:55
User entered 'Anxiety'	(b) (4), (b) (6)	22 Mar 2021 13:07:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 13:07:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Mar 2021 13:07:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Mar 2021 13:07:30

US3222452

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:04:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Mar 2021 13:07:30

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:21
User closed query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile. ' (Site from DM).		26 Apr 2021 16:14:40
Query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile. ' answered with 'ADDED DERMAL FILLER TO MH AND CONMED PAGES IN CRF AND SOURCE.' (Site from DM).	douglas winter (b) (4) (b) (4)	23 Apr 2021 15:57:40
User opened query 'Per CDM Review: The participant has indicated that they have received facial cosmetic injections on the Cosmetic Injection_ Dermal Filler eDiary form. However, there are no concomitant medications or medical history terms that correspond to a dermal filler. Please review and clarify or reconcile. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:30:05
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:34:22

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:37:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:37:38
Data point term sent to Coder	System	29 Sep 2020 17:36:30
User entered 'ASPIRIN'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'CARDIAC'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '81'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'mg (mg)'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1 Jan 2010'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	29 Sep 2020 17:35:49
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:35:49

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:35:49

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:35:49

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Sep 2020 17:38:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:38:40
Data point term sent to Coder	System	29 Sep 2020 17:37:30
User entered 'ATORVASTATIN'	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:36:47

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'HYPERLIPIDEMIA'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '20'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'mg (mg)'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1 Jan 1980'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	29 Sep 2020 17:36:47
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:36:47

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:36:47

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:36:47

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 15:48:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 15:48:21
Data point term sent to Coder	System	06 Nov 2020 15:47:14
Coding entries removed.	douglas winter (b) (4)	06 Nov 2020 15:46:19
User entered 'BUSPIRONE' reason for change: Data Entry Error	douglas winter (b) (4)	06 Nov 2020 15:46:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 22:56:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 22:56:43
Data point term sent to Coder	System	29 Sep 2020 17:38:32
User entered 'BUSIPRONE'	Alicia Cevera (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'DEPRESSION'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '5'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	douglas winter (b) (4)	06 Nov 2020 15:46:19
User entered 'once daily (QD)'	(b) (4)	
	Alicia Cevera (b) (4)	29 Sep 2020 17:37:56
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Oral (ORAL)'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '1 Jan 2000'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:22:36
User entered 'Yes (Y)'	(b) (4)	
	Alicia Cevera (b) (4)	29 Sep 2020 17:37:56
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:22:36
User entered empty.	(b) (4)	
	Alicia Cevera (b) (4)	29 Sep 2020 17:37:56
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User entered '2'	System	06 Nov 2020 15:46:19
User entered '1'	System	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User entered '1'	System	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:29
User entered '804 (804)'	System	29 Sep 2020 17:37:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 01:53:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 01:53:03
Data point term sent to Coder	System	11 Mar 2021 19:32:00
Coding entries removed.	Crystal Paccione (b) (4)	11 Mar 2021 19:31:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 18:12:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 18:12:30
Data point term sent to Coder	System	29 Sep 2020 17:40:39
User entered 'DULOXETINE'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 10:45:45
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match ' answered with 'noted' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:31:42
User entered 'NEUROPATHY (motor) (lower extremity)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:31:03
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 01:46:16
User entered 'NEUROPATHY'	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:40:23

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '60'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'mg (mg)'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1 Jan 2005'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	29 Sep 2020 17:40:23
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:40:23

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:40:23

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:40:23

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:42:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:42:43
Data point term sent to Coder	System	29 Sep 2020 17:41:44
User entered 'GLUCOSAMINE'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'SUPPLEMENT'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 10:45:26
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'dose not captured. Patient-reported 1tablet' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:32:45
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:10:27
User entered 'tablet (TABLET)'	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:41:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1 Jan 2005'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	29 Sep 2020 17:41:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:41:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:41:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:41:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	29 Sep 2020 17:44:48
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	29 Sep 2020 17:44:48
Data point term sent to Coders User entered 'LISINOPRIL'	System Alicia Cervera (b) (4) (b) (4)	29 Sep 2020 17:43:47 29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'HYPERTENSION'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '10'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'once daily (QD)'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Oral (ORAL)'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '1 Jan 1980'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) Alicia Cevera (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:24:13
User entered 'Yes (Y)'	(b) (4)	
	Alicia Cevera (b) (4)	29 Sep 2020 17:43:38
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:24:13
User entered empty.	(b) (4)	
	Alicia Cevera (b) (4)	29 Sep 2020 17:43:38
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User entered '1'	System	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User entered '1'	System	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:34
User entered '804 (804)'	System	29 Sep 2020 17:43:38

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 17:46:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:46:42
Data point term sent to Coder	System	29 Sep 2020 17:45:51
User entered 'MULTI-VITAMIN'	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:45:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'SUPPLEMENT'	(b) (4) Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:45:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'I'	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'tablet (TABLET)'	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'once daily (QD)'	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1 Jan 2007'	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	29 Sep 2020 17:45:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:45:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:45:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:45:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
Query 'Per MM: Please consider re-coding to PRESERVISION and S01XA.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 21:43:11
User opened query 'Per MM: Please consider re-coding to PRESERVISION and S01XA.' (Site from DM).		23 Oct 2020 16:13:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE, PRODUCTSYNONYM: PRESERVISION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:47:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:47:39
Data point term sent to Coder	System	29 Sep 2020 17:46:56
User entered 'PRESERVISION'	Alicia Cevera (b) (4) (b) (4)	29 Sep 2020 17:46:32

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'SUPPLEMENT'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'tablet (TABLET)'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'twice daily (BID)'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '1 Jan 2019'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '0'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	Alicia Cevera (b) (4)	29 Sep 2020 17:46:32
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Sep 2020 17:46:32

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:46:32

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:46:32

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 15:17:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 15:17:43
Data point term sent to Coder	System	19 Oct 2020 15:17:17
User entered 'tylenol'	(b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM re-query: Thank you for the response. However please confirm in query response that the solicited event "SORENESS AT INJECTION SITE" doesn't meet any of the AE reporting criteria per previous query. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:29:43
Query 'Per CDM re-query: Thank you for the response. However please confirm in query response that the solicited event "SORENESS AT INJECTION SITE" doesn't meet any of the AE reporting criteria per previous query. ' answered with 'This is a solicited event and does not meet AE criteria.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:40:59
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORENESS AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:45:10
User opened query 'Per CDM re-query: Thank you for the response. However please confirm in query response that the solicited event "SORENESS AT INJECTION SITE" doesn't meet any of the AE reporting criteria per previous query. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:45:08

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORENESS AT INJECTION SITE did not meet the AE reporting criteria.'	Crystal Paccione (b) (4)	11 Mar 2021 19:33:28
answered with 'this was a reported solicited event' (Site from DM). User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORENESS AT INJECTION SITE did not meet the AE reporting criteria.'	(b) (4), (b) (6)	15 Dec 2020 10:05:54
' (Site from DM). User entered 'soreness at injection site'		19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '1000'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '03 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '03 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User entered empty.	System	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User entered empty.	System	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:40
User entered empty.	System	19 Oct 2020 15:16:18

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:21:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:21:51
Data point term sent to Coder	System	22 Mar 2021 12:49:35
Coding entries removed.	(b) (4), (b) (6)	22 Mar 2021 12:49:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 03:51:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 03:51:47
Data point term sent to Coder	System	14 Dec 2020 18:10:25
Coding entries removed.	Albert Garcia (b) (4)	14 Dec 2020 18:09:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Dec 2020 14:20:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Dec 2020 14:20:48
Data point term sent to Coder	System	02 Dec 2020 16:27:31
Coding entries removed.	gail lavine (b) (4)	02 Dec 2020 16:26:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 14:57:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'MORPHINE'	Coder Import (b) (4) (b) (4) System douglas winter (b) (4) (b) (4)	06 Nov 2020 14:57:19 06 Nov 2020 14:40:49 06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM RQ: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF within the same timeframe. Please review if this should be changed to NO. Otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 10:31:27
Query 'Per DM RQ: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF within the same timeframe. Please review if this should be changed to NO. Otherwise clarify.' answered with 'CHANGED TO YES' (Site from DM).	douglas winter (b) (4) (b) (4)	23 Apr 2021 15:53:14
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Apr 2021 15:52:48
User opened query 'Per DM RQ: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF within the same timeframe. Please review if this should be changed to NO. Otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:27:49
Query 'Per DM RQ: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF and the indication matches with recorded AE's. Please review if this should be changed to NO. Otherwise clarify.' canceled (Site from DM).		23 Mar 2021 11:26:06
User opened query 'Per DM RQ: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF and the indication matches with recorded AE's. Please review if this should be changed to NO. Otherwise clarify.' (Site from DM).		23 Mar 2021 11:24:41
User closed query 'Per CDM re-query: There is AE / SAE corresponding to this indication and site response indicates "this is an SAE and is captured"; However the medication is reported to be given as Prophylactic on this form. Please update Prophylaxis and Indication field as appropriate else clarify in query response, ' (Site from DM).		23 Mar 2021 11:14:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Query 'Per CDM re-query: There is AE / SAE corresponding to this indication and site response indicates "this is an SAE and is captured"; However the medication is reported to be given as Prophylactic on this form. Please update Prophylaxis and Indication field as appropriate else clarify in query response, ' answered with 'Updated to pain. indication was incorrect' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:50:03
User closed query 'Per DM CLR: Prophylaxis=yes. Please review if this should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate.		12 Mar 2021 10:40:35
' (Site from DM).		
User opened query 'Per CDM re-query: There is AE / SAE corresponding to this indication and site response indicates "this is an SAE and is captured"; However the medication is reported to be given as Prophylactic on this form. Please update Prophylaxis and Indication field as appropriate else clarify in query response, ' (Site from DM).		12 Mar 2021 10:40:33
Query 'Per DM CLR: Prophylaxis=yes. Please review if this should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate.	Crystal Paccione (b) (4)	11 Mar 2021 19:34:22
' answered with 'this is an SAE and is captured' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis=yes. Please review if this should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate.	(b) (4), (b) (6)	22 Jan 2021 03:16:21
' (Site from DM).		
User entered 'Yes (Y)'	douglas winter (b) (4)	06 Nov 2020 14:40:25
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Pain PRN- CERVICAL SPINE PAIN, NASAL FRACTURE AND FACIAL LACERATION SECONDARY TO FALL' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 12:49:35
User closed query 'Per DM CLR: Please update the indication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for CERVICAL SPINE PAIN, NASAL FRACTURE AND FACIAL LACERATION SECONDARY TO FALL). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:44:31
Query 'Per DM CLR: Please update the indication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for CERVICAL SPINE PAIN, NASAL FRACTURE AND FACIAL LACERATION SECONDARY TO FALL). Update Con Med eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	14 Dec 2020 18:09:58
User entered 'PROPHYLAXIS - CERVICAL SPINE PAIN, NASAL FRACTURE AND FACIAL LACERATION SECONDARY TO FALL' reason for change: Data Entry Error	(b) (4)	14 Dec 2020 18:09:48
User opened query 'Per DM CLR: Please update the indication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for CERVICAL SPINE PAIN, NASAL FRACTURE AND FACIAL LACERATION SECONDARY TO FALL). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:40:00
User entered 'cervical spine pain, nasal fracture and facial laceration secondary to fall' reason for change: Data Entry Error	gail lavine (b) (4)	02 Dec 2020 16:26:35
User entered 'PAIN MANAGEMENT'	douglas winter (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '2'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'EVERY 2 HOURS/PRN'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '27 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:40:25
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 14:17:09
User entered 'Yes (Y)'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:40:25
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 14:17:09
User entered empty.	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:40:25
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User entered empty.	System	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User entered empty.	System	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:28:55
User entered empty.	System	06 Nov 2020 14:40:25

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 17:54:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 17:54:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 19:39:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 19:39:09
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	14 Dec 2020 18:13:28 14 Dec 2020 18:12:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 14:59:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 14:59:17
Data point term sent to Coder	System	06 Nov 2020 14:46:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'NORMAL SALINE'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:46:20
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for HYDRATION). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 12:44:40
Query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for HYDRATION). Update Con Med eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:12:35
User entered 'DIHYDRATION - PROPHYLAXIS' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:12:30
User opened query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for HYDRATION). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:41:42
User entered 'HYDRATION'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '1000'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mL (mL)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:46:20
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'once (ONCE)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:46:20
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '28 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:17:28
User entered 'Yes (Y)'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:46:20
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:17:28
User entered empty.	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:46:20
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User entered empty.	System	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User entered empty.	System	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:03
User entered empty.	System	06 Nov 2020 14:46:20

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 14:03:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 14:03:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 11:49:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 11:49:05
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Mar 2021 12:51:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 23:50:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 23:50:16
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	14 Dec 2020 18:13:26

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:16:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:16:17
Data point term sent to Coder	System	06 Nov 2020 14:53:05
User entered 'SODIUM CHLORIDE' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:52:07
Data point term sent to Coder	System	06 Nov 2020 14:47:58
User entered 'SALINE FLUSH'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:09:38
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'updated' (Site from DM).		22 Mar 2021 12:51:30
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).		19 Mar 2021 08:09:15
User closed query 'Per CDM: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' (Site from DM).		12 Mar 2021 10:34:19
Query 'Per CDM: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' answered with 'this is prophylaxis given in the hospital ' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:36:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:35:36
User opened query 'Per CDM: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:57:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:57:15
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Updated' (Site from DM).		11 Feb 2021 21:12:09
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).		22 Jan 2021 03:32:16
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'DIHYDRATION -' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 12:51:15
User closed query 'Per DM CLR: Please review the Indication and update to provide the medical condition that this medication was used to Prevent/Treat rather than the action.' (Site from DM).		17 Dec 2020 13:48:02
Query 'Per DM CLR: Please review the Indication and update to provide the medical condition that this medication was used to Prevent/Treat rather than the action.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:13:20
User entered 'DIHYDRATION - PROPHYLAXIS' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:13:16
User opened query 'Per DM CLR: Please review the Indication and update to provide the medical condition that this medication was used to Prevent/Treat rather than the action.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:42:46
User entered 'HYDRATION' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:52:07
User entered 'KEEP VEIN OPEN'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '250' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:52:07
User entered '10'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:47:48
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mL (mL)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:52:45
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:52:07
User entered 'as needed (PRN)'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:47:48
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Intravenous Drip (INTRAVENOUS DRIP)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:52:07
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:47:48
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '27 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:47:48
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:18:13
User entered 'Yes (Y)'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:47:48
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:18:13
User entered empty.	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:47:48
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User entered empty.	System	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User entered empty.	System	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:09
User entered empty.	System	06 Nov 2020 14:47:48

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 16:58:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 16:58:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Dec 2020 01:38:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Dec 2020 01:38:55
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	14 Dec 2020 18:15:30 14 Dec 2020 18:15:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SALINE [SODIUM CHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 14:52:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 14:52:17
Data point term sent to Coder	System	06 Nov 2020 14:51:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'SALINE FLUSH'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Prophylaxis = No. However, this medication is used as a prevention for clotting in the intravenous line. Please review and update Prophylaxis to Yes as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 13:48:11
Query 'Per DM CLR: Prophylaxis = No. However, this medication is used as a prevention for clotting in the intravenous line. Please review and update Prophylaxis to Yes as applicable. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:13:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:13:48
User opened query 'Per DM CLR: Prophylaxis = No. However, this medication is used as a prevention for clotting in the intravenous line. Please review and update Prophylaxis to Yes as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:45:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 13:34:39
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'RELATED TO LOG LINE 10' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:15:17
User entered 'LACERATION SECONDARY TO FALL' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:15:05
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:43:26
User entered 'KEEP VEIN OPEN'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '10'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mL (mL)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'EVERY 12 HOURS/PRN'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '27 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:50:15
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:18:56
User entered 'Yes (Y)'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:50:15
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:18:56
User entered empty.	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:50:15
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User entered empty.	System	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User entered empty.	System	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:12
User entered empty.	System	06 Nov 2020 14:50:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 06:57:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 06:57:29
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Mar 2021 12:53:37 22 Mar 2021 12:52:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 14:57:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 14:57:18
Data point term sent to Coder User entered 'ONDANSETRON'	System douglas winter (b) (4)	06 Nov 2020 14:56:08 06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to AE as there is there is a medical condition if SUBDURAL HEMATOMA recorded that matches this medication and used within the same timeframe. Please confirm if this Con Med is given for this medical condition. Update indication and this field to "No" as appropriate. Else, clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:13:04
Query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to AE as there is there is a medical condition if SUBDURAL HEMATOMA recorded that matches this medication and used within the same timeframe. Please confirm if this Con Med is given for this medical condition. Update indication and this field to "No" as appropriate. Else, clarify. Thank you. ' answered with 'con med given for AE of subdural hematoma' (Site from DM).		22 Mar 2021 12:54:01
User entered 'No (N)' reason for change: Data Entry Error		22 Mar 2021 12:53:55
User opened query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to AE as there is there is a medical condition if SUBDURAL HEMATOMA recorded that matches this medication and used within the same timeframe. Please confirm if this Con Med is given for this medical condition. Update indication and this field to "No" as appropriate. Else, clarify. Thank you. ' (Site from DM).		19 Mar 2021 08:53:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:36:59
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM re-query: Response indicates 'this is a prophylaxis given in the hospital'. Please update the indication term to reflect the prophylactic condition. Thank you. ' (Site from DM). Query 'Per CDM re-query: Response indicates 'this is a prophylaxis given in the hospital'. Please update the indication term to reflect the prophylactic condition. Thank you. ' answered with 'updated' (Site from DM) User entered 'NAUSEA due to subdural hematoma' reason for change: Data Entry Error User closed query 'Per DM CLR RQ: Previous response noted,however on reviewing AE eCRF, there is no record of "Nausea" present. Please review and update the details accordingly,else clarify.' (Site from DM). User opened query 'Per CDM re-query: Response indicates 'this is a prophylaxis given in the hospital'. Please update the indication term to reflect the prophylactic condition. Thank you. ' (Site from DM). Query 'Per DM CLR RQ: Previous response noted,however on reviewing AE eCRF, there is no record of "Nausea" present. Please review and update the details accordingly,else clarify.' answered with 'this is a prophylaxis given in the hospital' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:13:06 22 Mar 2021 12:54:11 22 Mar 2021 12:52:45 12 Mar 2021 10:42:44 12 Mar 2021 10:42:42
User opened query 'Per DM CLR RQ: Previous response noted,however on reviewing AE eCRF, there is no record of "Nausea" present. Please review and update the details accordingly,else clarify.' (Site from DM).	Crystal Paccione (b) (4)	11 Mar 2021 19:37:39
User opened query 'Per DM CLR RQ: Previous response noted,however on reviewing AE eCRF, there is no record of "Nausea" present. Please review and update the details accordingly,else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:11:35
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:11:35

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'RELATED TO LISTED SAE' (Site from DM).	Albert Garcia (b) (4)	14 Dec 2020 18:16:04
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:46:01
User entered 'NAUSEA'	douglas winter (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '4'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:55:44
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4)	06 Nov 2020 14:55:44
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 12:52:45
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '27 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 16:19:51
User entered 'Yes (Y)'	douglas winter (b) (4)	06 Nov 2020 14:55:44
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:19:51
User entered empty.	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 14:55:44
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User entered empty.	System	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User entered empty.	System	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:18
User entered empty.	System	06 Nov 2020 14:55:44

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 15:40:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 15:40:51
Data point term sent to Coder	System	14 Dec 2020 18:17:31
Coding entries removed.	Albert Garcia (b) (4)	14 Dec 2020 18:16:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 05:21:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 05:21:00
Data point term sent to Coder	System	02 Dec 2020 16:29:36
Coding entries removed.	gail lavine (b) (4)	02 Dec 2020 16:28:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:30:22

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:30:22
Data point term sent to Coder	System	06 Nov 2020 17:35:27
User entered 'ACETAMINOPHEN-HYDROCODONE'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Prophylaxis=yes. Please review if this should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 10:41:05
Query 'Per DM CLR: Prophylaxis=yes. Please review if this should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'corrected per query' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:38:49
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:38:37
User opened query 'Per DM CLR: Prophylaxis=yes. Please review if this should be changed to NO as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 02:21:57
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for SUBDURAL HEMATOMA, NASAL FRACTURE, AND FACIAL LACERATION PAIN). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 12:44:51
Query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for SUBDURAL HEMATOMA, NASAL FRACTURE, AND FACIAL LACERATION PAIN). Update Con Med eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:16:47
User entered 'SUBDURAL HEMATOMA, NASAL FRACTURE, AND FACIAL LACERATION PAIN - PROPHYLAXIS' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Dec 2020 18:16:42
User opened query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for SUBDURAL HEMATOMA, NASAL FRACTURE, AND FACIAL LACERATION PAIN). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:47:08
User entered 'subdural hematoma, nasal fracture, and facial laceration pain' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 16:28:36
User entered 'PAIN MANAGEMENT'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '325-5' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:20:33
User entered '5-325'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 17:34:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:34:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:34:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:34:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '28 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:34:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 17:35:48
User entered 'Yes (Y)'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 17:34:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 17:35:48
User entered empty.	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 17:34:39
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User entered empty.	System	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User entered empty.	System	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:23
User entered empty.	System	06 Nov 2020 17:34:39

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #03 BUSPIRONE / (Start date 01Jan2000 - Stop date 30Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 11:02:27
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #03 BUSPIRONE / (Start date 01Jan2000 - Stop date 30Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'one is PRN and one BID' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:42:07
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #03 BUSPIRONE / (Start date 01Jan2000 - Stop date 30Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:48:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:41:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:41:20
Data point term sent to Coder	System	06 Nov 2020 17:40:37
User entered 'BUSPIRONE'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:40:02
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'ANXIETY'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '5'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:40:02
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:40:02
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:40:02
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '28 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	13 Nov 2020 16:21:43
User entered '29 Oct 2020'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 17:40:02
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User entered empty.	System	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User entered empty.	System	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:29
User entered empty.	System	06 Nov 2020 17:40:02

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:01:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:01:02
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	23 Apr 2021 15:56:08 23 Apr 2021 15:55:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:18:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:18:32
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Mar 2021 12:55:38 22 Mar 2021 12:54:56

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:44:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:44:40
Data point term sent to Coder	System	11 Mar 2021 19:44:13
Coding entries removed.	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:43:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:34:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:34:29
Data point term sent to Coder	System	06 Nov 2020 17:58:07
User entered 'ROCEPHIN'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR RQ: Response noted, please update the indication to specify which AE this medication was given for. If used as prophylaxis, please update back to 'Yes'. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 10:32:13
Query 'Per DM CLR RQ: Response noted, please update the indication to specify which AE this medication was given for. If used as prophylaxis, please update back to 'Yes'. ' answered with 'ADDED AE INDICATION' (Site from DM).	douglas winter (b) (4) (b) (4)	23 Apr 2021 15:56:04
User opened query 'Per DM CLR RQ: Response noted, please update the indication to specify which AE this medication was given for. If used as prophylaxis, please update back to 'Yes'. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 04:22:04
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 15:35:45
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'given for AE - updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:55:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 12:54:45
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 08:10:28

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'AE # 1	(b) (4)	
INFECTION PREVENTATIVE' reason for change:	douglas winter (b) (4)	23 Apr 2021 15:55:42
Data Entry Error	(b) (4)	
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) (6)	12 Mar 2021 11:02:49
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 'added infection' (Site from DM).	Crystal Paccione (b) (4)	11 Mar 2021 19:43:37
User entered 'infection PREVENTATIVE' reason for change: Data Entry Error	(b) (4)	11 Mar 2021 19:43:23
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)	09 Dec 2020 15:48:29
User entered 'PREVENTATIVE'	douglas winter (b) (4)	06 Nov 2020 17:57:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'g (g)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'once (ONCE)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:57:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 12:54:56
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '26 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:57:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '26 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 17:57:33
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User entered empty.	System	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User entered empty.	System	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:35
User entered empty.	System	06 Nov 2020 17:57:33

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 11:35:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 11:35:43
Data point term sent to Coder	System	11 Mar 2021 19:45:13
Coding entries removed.	Crystal Paccione (b) (4)	11 Mar 2021 19:44:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:15:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 08:15:28
Data point term sent to Coder	System	06 Nov 2020 18:44:11
User entered 'FAMOTIDINE'	douglas winter (b) (4)	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 18:43:17
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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)	12 Mar 2021 11:02:58
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 'added heartburn' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:44:42
User entered 'heartburn PREVENTATIVE' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:44:18
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)	09 Dec 2020 15:48:48
User entered 'PREVENTATIVE'	douglas winter (b) (4) (b) (4)	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '20'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 18:43:17
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4)	06 Nov 2020 18:43:17
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 18:43:53
User entered '27 Oct 2020'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 18:43:17
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 18:43:53
User entered 'Yes (Y)'	(b) (4)	
	douglas winter (b) (4)	06 Nov 2020 18:43:17
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	06 Nov 2020 18:44:48
User entered '29 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	06 Nov 2020 18:44:48
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	06 Nov 2020 18:43:53
User entered empty.	douglas winter (b) (4)	06 Nov 2020 18:43:17
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User entered empty.	System	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User entered empty.	System	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:38
User entered empty.	System	06 Nov 2020 18:43:17

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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)	18 Dec 2020 18:36:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:36:40
Data point term sent to Coder Coding entries removed.	System gail lavine (b) (4)	02 Dec 2020 16:23:26 02 Dec 2020 16:22:53
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)	07 Nov 2020 07:17:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:17:29
Data point term sent to Coder User entered 'NICARDIPINE'	System douglas winter (b) (4)	06 Nov 2020 21:13:59 06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:13:51
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'subdural hematoma' reason for change: Data Entry Error	(b) (4)	
	gail lavine (b) (4)	02 Dec 2020 16:22:53
	(b) (4)	
User entered 'HEAD INJURY'	douglas winter (b) (4)	06 Nov 2020 21:13:51
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '25'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:13:51
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '5MG/HR'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '27 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:13:51
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:13:51
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '28 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:13:51
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User entered empty.	System	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User entered empty.	System	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:43
User entered empty.	System	06 Nov 2020 21:13:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 10:46:26
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'not a worsening, this was given in the hospital' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	11 Mar 2021 19:47:25
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:51:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:29
Data point term sent to Coder	System	06 Nov 2020 21:33:30
User entered 'LABETALOL'	douglas winter (b) (4) (b) (4)	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:32:55
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'HYPERTENSION'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '10'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:32:55
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:32:55
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:32:55
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '27 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:32:55
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:32:55
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '27 Oct 2020'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:32:55
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	06 Nov 2020 21:32:55
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User entered '2'	System	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User entered '1'	System	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:48
User entered '804 (804)'	System	06 Nov 2020 21:32:55

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Nov 2020 16:27:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:27:02
Data point term sent to Coder	System	13 Nov 2020 16:26:19
User entered 'BUSPIRONE'	douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 16:04:07

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM re-query: Thank you for the response. However the medical condition that occur after the first dose need to be added in AE eCRF. Please add the AE of Anxiety in AE eCRF as appropriate else clarify. ' (Site from DM).	(b) (4)	23 Mar 2021 11:31:02
Query 'Per CDM re-query: Thank you for the response. However the medical condition that occur after the first dose need to be added in AE eCRF. Please add the AE of Anxiety in AE eCRF as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:08:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).		12 Mar 2021 10:50:12
User opened query 'Per CDM re-query: Thank you for the response. However the medical condition that occur after the first dose need to be added in AE eCRF. Please add the AE of Anxiety in AE eCRF as appropriate else clarify. ' (Site from DM).		12 Mar 2021 10:50:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'this was given to the patient in the hospital' (Site from DM).	Crystal Paccione (b) (4)	11 Mar 2021 19:48:27
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:51:50
User entered 'ANXIETY'	douglas winter (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '5'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	13 Nov 2020 16:26:05
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	13 Nov 2020 16:26:05
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '30 Oct 2020'	douglas winter (b) (4)	13 Nov 2020 16:26:05
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 16:26:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 10:50:30
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'no worsening, medication was given in the hospital' (Site from DM).	Crystal Paccione (b) (4)	11 Mar 2021 19:49:49
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:52:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:27:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:27:46
Data point term sent to Coder	System	13 Nov 2020 16:27:20
User entered 'LISINOPRIL'	douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	13 Nov 2020 16:27:00
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'HYPERTENSION'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '40'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered 'mg (mg)'	douglas winter (b) (4)	13 Nov 2020 16:27:00
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'once daily (QD)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered '30 Oct 2020'	douglas winter (b) (4)	13 Nov 2020 16:27:00
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
User entered empty.	douglas winter (b) (4)	13 Nov 2020 16:27:00
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 16:27:00

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM re-query: Please review the start/stop date of this medication (LISINOPRIL 27 OCT 2020 - 28 OCT 2020) as it overlaps with the Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please reconcile the stop date of CM #6 and start date of CM # 23 and update if appropriate else provide explanation in query response. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:38:59
Query 'Per CDM re-query: Please review the start/stop date of this medication (LISINOPRIL 27 OCT 2020 - 28 OCT 2020) as it overlaps with the Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please reconcile the stop date of CM #6 and start date of CM # 23 and update if appropriate else provide explanation in query response. ' answered with 'updated per hospital DC records' (Site from DM).		22 Mar 2021 13:18:58
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).		12 Mar 2021 10:57:53
User opened query 'Per CDM re-query: Please review the start/stop date of this medication (LISINOPRIL 27 OCT 2020 - 28 OCT 2020) as it overlaps with the Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please reconcile the stop date of CM #6 and start date of CM # 23 and update if appropriate else provide explanation in query response. ' (Site from DM).		12 Mar 2021 10:57:51

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'this was stopped in the hospital and other medications were given' (Site from DM).	Crystal Paccione (b) (4)	11 Mar 2021 19:51:01
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:52:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 16:30:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 16:30:55
Data point term sent to Coder	System	13 Nov 2020 16:30:23
User entered 'LISINOPRIL'	douglas winter (b) (4)	13 Nov 2020 16:30:05
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:30:05
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'HYPERTENSION'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '20'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:30:05
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	22 Mar 2021 13:18:22
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	22 Mar 2021 13:18:22
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Mar 2021 13:17:11
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	22 Mar 2021 13:17:11
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:17:11
User entered 'other (OTHER)'	douglas winter (b) (4)	13 Nov 2020 16:30:05
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:18:22
User entered 'X 2 TABS ONE TIME'	douglas winter (b) (4) (b) (4)	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '27 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:30:05
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:18:22
User entered '28 Oct 2020'	douglas winter (b) (4) (b) (4)	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:30:05
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User entered empty.	System	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User entered empty.	System	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:54
User entered empty.	System	13 Nov 2020 16:30:05

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User closed query 'Per CDM re-query: Please review the start/stop date of this medication (LISINOPRIL 28 OCT 2020 - 29 OCT 2020) as it overlaps with the Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please reconcile the stop date of CM #6 and start date of CM # 24 and update if appropriate else provide explanation in query response. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:39:31
Query 'Per CDM re-query: Please review the start/stop date of this medication (LISINOPRIL 28 OCT 2020 - 29 OCT 2020) as it overlaps with the Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please reconcile the stop date of CM #6 and start date of CM # 24 and update if appropriate else provide explanation in query response. ' answered with 'updated per hospital DC summary' (Site from DM).		22 Mar 2021 13:20:37
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).		12 Mar 2021 10:59:25
User opened query 'Per CDM re-query: Please review the start/stop date of this medication (LISINOPRIL 28 OCT 2020 - 29 OCT 2020) as it overlaps with the Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please reconcile the stop date of CM #6 and start date of CM # 24 and update if appropriate else provide explanation in query response. ' (Site from DM).		12 Mar 2021 10:59:23

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

Name of Medication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'this was stopped when the patient was hospitalized and other medications were given' (Site from DM).	Crystal Paccione (b) (4)	11 Mar 2021 19:51:47
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #06 LISINOPRIL / (Start date 01Jan1980 - 30Oct2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:53:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 16:32:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 16:32:46
Data point term sent to Coder	System	13 Nov 2020 16:32:26
User entered 'LISINOPRIL'	douglas winter (b) (4)	13 Nov 2020 16:31:34
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:31:34
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'HYPERTENSION'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '30'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:31:34
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:31:34
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:20:18
User entered 'other (OTHER)'	douglas winter (b) (4) (b) (4)	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:20:18
User entered 'X 3 TABS ONE TIME ONLY'	douglas winter (b) (4) (b) (4)	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:31:34
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '28 Oct 2020'	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:31:34
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:31:34
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:20:18
User entered '29 Oct 2020'	douglas winter (b) (4) (b) (4)	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	13 Nov 2020 16:31:34
	(b) (4)	

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User entered empty.	System	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User entered empty.	System	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:29:58
User entered empty.	System	13 Nov 2020 16:31:34

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: OTHER DERMATOLOGICALS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:01:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:01:03
Data point term sent to Coder	System	23 Apr 2021 16:00:12
User entered 'UNKNOWN DERMAL FILLER'	douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'COSMETIC'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'UNKNOWN'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'UNITS'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'unknown (UNKNOWN)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'UN UNK 0000'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User entered empty.	System	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User entered empty.	System	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:04:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:10:36
User entered empty.	System	23 Apr 2021 15:59:15

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:04:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	gail lavine (b) (4)	02 Dec 2020 16:34:59
User entered 'No (N)'	(b) (4)	
	Albert Garcia (b) (4)	09 Oct 2020 18:15:56
	(b) (4)	

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '26 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 17:02:34

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'CT maxillofacial without contracet'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 17:02:34

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 17:02:34

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:04:07

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 17:02:34

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:04:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:53
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '26 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 17:03:32

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:04:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:53
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'CT cervial spine without contrast'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 17:03:32

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:53
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 17:03:32

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:04:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:38:53
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 17:03:32

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:04:07

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '26 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:02:42

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:04:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Cat scan head and brain'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:02:42

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:02:42

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:04:07

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:02:42

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:04:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:06
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '26 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:19:57

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:04:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:06
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'physical therapy'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:19:57

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:06
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:19:57

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:04:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:06
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:19:57

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:04:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '26 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:20:33

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:04:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Occupational therapy'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:20:33

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:20:33

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:04:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:09
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:20:33

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:04:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '26 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:21:24

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:04:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'flexion extension x-ray of cervical spine'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:21:24

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:21:24

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:04:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:13
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:21:24

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:04:07

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '26 Oct 2020'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:22:06

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:04:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'cervical collar'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:22:06

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:04:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'Adverse Event (AE)'	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:22:06

US3222452

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:04:07

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:39:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	07 Dec 2020 13:22:06

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '30/Oct/2020 13:00'	(b) (4) System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'I'		30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '09/Nov/2020 08:11'	(b) (4) System	09 Nov 2020 13:11:57

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 02:12:54
User entered 'I'		09 Nov 2020 13:11:57

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '12/Nov/2020 02:13'	(b) (4) System	12 Nov 2020 02:13:10

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:33
User entered 'I'		12 Nov 2020 02:13:10

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '12/Nov/2020 20:10'	(b) (4) System	12 Nov 2020 20:10:51

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:28:56
User entered 'I'		12 Nov 2020 20:10:51

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:04:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '16/Nov/2020 21:29'	(b) (4) System	16 Nov 2020 21:29:43

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:04:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:41:29
User entered 'I'		16 Nov 2020 21:29:43

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:04:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '03/Dec/2020 12:41'	(b) (4) System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:04:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'I'	(b) (4), (b) (6)	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:04:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered '07/Dec/2020 09:52'	(b) (4) System	07 Dec 2020 14:52:59

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:04:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:20:44
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:52:59

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:04:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '12/Mar/2021 09:20'	(b) (4) System	12 Mar 2021 15:21:08

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:04:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:21:08

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'USA-US104-2020-MRNA-1273-P301000014'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'No (N)'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Bruce'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Lisa'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Tracy'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Rankin'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
Un-reviewed for Safety.	System	03 Dec 2020 17:41:46
User entered 'Holloway'	System	03 Dec 2020 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 13:00:10
User entered 'Kowalski'	System	30 Oct 2020 12:59:24

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '860 Peachwood Ave'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '6550 Mapleridge Street'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered 'Deland'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'Houston'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered empty.	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered 'TX'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
	(b) (4)	
Un-reviewed for Safety.	System	12 Mar 2021 15:21:08
Signature has been broken.	System	12 Mar 2021 15:21:08
User entered '32720'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 14:50:57
User entered '77081'	System	03 Dec 2020 17:41:46

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:11:49
User entered 'US'	System	30 Oct 2020 13:00:18

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Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	23 Mar 2021 14:40:15
User entered '8'	System	12 Mar 2021 15:21:08
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:37:16
	(b) (4)	
User entered '7'	System	07 Dec 2020 14:52:59
User entered '6'	System	03 Dec 2020 17:41:46
User entered '5'	System	16 Nov 2020 21:29:43
User entered '4'	System	12 Nov 2020 20:10:51
User entered '3'	System	12 Nov 2020 02:13:10
User entered '2'	System	09 Nov 2020 13:11:57
User entered '1'	System	30 Oct 2020 13:00:18

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:04:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered '23/Mar/2021 10:40'	(b) (4) System	23 Mar 2021 14:40:15

US3222452

Folder: SAE USA-US104-2020-MRNA-1273-P301000014

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:04:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:40:15