

US3222554 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:06:57

All time stamps listed in this document are displayed in GMT

US3222554

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 20:41:51

Generated On: 09 Jun 2021 16:06:57

[Participant ID](#)

US3222554

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

US3222554

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 20:41:52

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Date of Informed Consent (<i>dd MMM yyyy</i>)	7 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 20:41:52

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 20:41:52

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 20:41:52

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Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN 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)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 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)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 SEP 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	7 SEP 2020 10:25
Height (xxx.x)	167.6 cm
Weight (xxx.x)	81.6 kg
BMI (xxx.x)	29.04973 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:41:52

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 20:41:52

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

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 20:41:52

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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 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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 20:41:52

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What was the date of randomization? (dd MMM yyyy) 07 SEP 2020

What was the participant's randomization number? 190174

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 20:41:52

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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 20:41:52

Generated On: 09 Jun 2021 16:06:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	7 SEP 2020 10:30
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 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 20:41:52

Generated On: 09 Jun 2021 16:06:57

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 SEP 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	7 SEP 2020 11:40
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 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 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 7 SEP 2020

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

Treatment Date and Time (derived) 7 SEP 2020 11:05

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 SEP 2020
Collection time (00:00-23:59)	11:00 (24 HR)
Collection date and time (derived)	7 SEP 2020 11:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Collection date (dd MMM yyyy)			7 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:01	7 SEP 2020 11:01
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 SEP 2020 11:25

PC Close Date & Time

07 SEP 2020 13:55

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.4 °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	07 SEP 2020 19:54
PC Open Date & Time	07 SEP 2020 14:50
PC Close Date & Time	08 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 02:06

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

10 SEP 2020 08:52

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

10 SEP 2020 23:36

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

11 SEP 2020 21:42

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

12 SEP 2020 18:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

13 SEP 2020 15:44

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

07 SEP 2020 11:25

PC Close Date & Time

07 SEP 2020 13:55

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

Please record - **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

07 SEP 2020 19:55

PC Open Date & Time

07 SEP 2020 14:50

PC Close Date & Time

08 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

Please record - **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

09 SEP 2020 02:07

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 08:52

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 23:37

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 21:43

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 18:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 15:44

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

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

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 11:25

PC Close Date & Time

07 SEP 2020 13:55

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

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

No ☒

Yes ☐

PC Time stamp	07 SEP 2020 19:56
PC Open Date & Time	07 SEP 2020 14:50
PC Close Date & Time	08 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 02:08
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 08:53
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 23:37
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2253

EAB) (1725)

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2253

EAB) (1725)

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:32
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2253

EAB) (1725)

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 15:45
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3222554

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:41:53

Generated On: 09 Jun 2021 16:06:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:43:19

Generated On: 09 Jun 2021 16:06:57

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	11:01 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:01
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:43:19

Generated On: 09 Jun 2021 16:06:57

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	12:57 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:57
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3222554

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:41:53

Generated On: 09 Jun 2021 16:06:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3222554

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:41:53

Generated On: 09 Jun 2021 16:06:57

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 7 OCT 2020

What was the treatment time? (00:00-23:59) 12:15 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 12:15

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

US3222554

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:41:53

Generated On: 09 Jun 2021 16:06:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	11:26 (24 HR)
Collection date and time (derived)	7 OCT 2020 11:26

US3222554

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:41:53

Generated On: 09 Jun 2021 16:06:57

Collection date (dd MMM yyyy)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	7 OCT 2020 11:30
Nasopharyngeal Swab 2	No		

US3222554

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:53

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 12:44

PC Open Date & Time

07 OCT 2020 12:35

PC Close Date & Time

07 OCT 2020 15:05

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.8 °F

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

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

PC Time Stamp	08 OCT 2020 08:43
PC Open Date & Time	07 OCT 2020 16:00
PC Close Date & Time	08 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

08 OCT 2020 23:21

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

10 OCT 2020 08:03

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

10 OCT 2020 19:21

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

11 OCT 2020 13:21

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

12 OCT 2020 14:11

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

14 OCT 2020 09:29

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 12:45

PC Open Date & Time

07 OCT 2020 12:35

PC Close Date & Time

07 OCT 2020 15:05

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

Please record - **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

08 OCT 2020 08:43

PC Open Date & Time

07 OCT 2020 16:00

PC Close Date & Time

08 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

Please record - **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 23:22

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 08:03

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 19:22

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 OCT 2020 13:21

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 14:12

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 09:30

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 12:46
PC Open Date & Time	07 OCT 2020 12:35
PC Close Date & Time	07 OCT 2020 15:05

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 08:44
PC Open Date & Time	07 OCT 2020 16:00
PC Close Date & Time	08 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 23:22
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 08:03
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 2253

EAB) (1725)

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 19:23
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 13:22
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 14:12
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 09:30
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3222554

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:43:19

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:43:19

Generated On: 09 Jun 2021 16:06:57

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222554

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:43:19

Generated On: 09 Jun 2021 16:06:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3222554

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:43:19

Generated On: 09 Jun 2021 16:06:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 NOV 2020

Collection time (00:00-23:59)

09:00 (24 HR)

Collection date and time (derived)

9 NOV 2020 09:00

US3222554

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:43:19

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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 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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 103

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 22:04:05

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 138

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 152

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 19:08:07

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 173

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 187

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 208

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 222

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 257

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2021 00:01
Patient Cloud Close Date & Time	27 JUN 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2021 00:01
Patient Cloud Close Date & Time	11 JUL 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 348

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

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

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

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

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

Patient Cloud Open Date & Time	15 SEP 2021 00:01
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Patient Cloud Close Date & Time	19 SEP 2021 23:59
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US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 383

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 495

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 523

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 537

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 544

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 593

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

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

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

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

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

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

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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 642

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 684

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

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

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

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

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

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

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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 705

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

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

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

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

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

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

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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 726

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	31 AUG 2022 00:01
Patient Cloud Close Date & Time	04 SEP 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3222554

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:06:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		19 APR 2021 17:24:40

US3222554

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:27:45

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:27:45

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 15:04:45

Generated On: 09 Jun 2021 16:06:57

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

Visit date (dd MMM yyyy)	15 APR 2021
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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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US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 15:04:45

Generated On: 09 Jun 2021 16:06:57

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222554

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 15:04:45

Generated On: 09 Jun 2021 16:06:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3222554

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 15:04:45

Generated On: 09 Jun 2021 16:06:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 APR 2021
Collection time (00:00-23:59)	11:00 (24 HR)
Collection date and time (derived)	15 APR 2021 11:00

US3222554

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 15:04:45

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222554

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:06:57

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3222554

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:06:57

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222554

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3222554

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 17:44:09

Generated On: 09 Jun 2021 16:06:57

Date of updated informed consent (<i>dd MMM yyyy</i>)	31 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	31 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3222554

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Height

Weight

BMI (xxx.x)

US3222554

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3222554

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 FEB 2021
Time of assessment (00:00-23:59)	12:26 (24 HR)
Vital Signs Date and Time (derived)	14 FEB 2021 12:26
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3222554

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 FEB 2021

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

US3222554

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:41:51

Generated On: 09 Jun 2021 16:06:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 14 FEB 2021

What was the treatment time? (00:00-23:59) 11:56 (24 HR)

Treatment Date and Time (derived) 14 FEB 2021 11:56

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

US3222554

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:41:52

Generated On: 09 Jun 2021 16:06:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 FEB 2021

Collection time (00:00-23:59)

11:30 (24 HR)

Collection date and time (derived)

14 FEB 2021 11:30

US3222554

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 20:41:51

Generated On: 09 Jun 2021 16:06:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 FEB 2021
Collection time (00:00 - 23:59)	11:33
Collection Date and Time (derived)	14 FEB 2021 11:33

US3222554

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:41:51

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:53:26

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:53:26

Generated On: 09 Jun 2021 16:06:57

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

US3222554

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	OLD29

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 10:26
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 11:08
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3222554

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3222554

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 15 MAR 2021

What was the treatment time? (00:00-23:59) 10:38 (24 HR)

Treatment Date and Time (derived) 15 MAR 2021 10:38

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

US3222554

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:41:17

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:44:10

Generated On: 09 Jun 2021 16:06:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222554

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:44:09

Generated On: 09 Jun 2021 16:06:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222554

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 APR 2021
Collection time (00:00-23:59)	11:00 (24 HR)
Collection date and time (derived)	15 APR 2021 11:00

US3222554

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 20:41:51

Generated On: 09 Jun 2021 16:06:57

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

AEID	USA-US104-2021-MRNA-1273-P30 1000006
Adverse event	DIVERTICULITIS
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)	24 JAN 2021
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)	07 FEB 2021
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)	28 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	30 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3222554

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

PATIENT HERE FOR
PARTICIPATION DECISION
CLINIC VISIT, PT STATED HE
WAS ADMITTED TO THE
HOSPITAL FOR DIVERTICULITIS
ON JAN 29 2021 AND WAS
DISCHARGED ON JAN 30 2021.
PATIENT STATED HIS
SYMPTOMS OF ABDOMINAL
PAIN STARTED ON JAN 24TH
2021 AND SAW HIS PCP AND
WAS GIVEN ORAL ANTIBIOTICS
BUT THE PAIN PERSISTED AND
PATIENT SOUGHT MEDICAL
ATTENTION AT THE HOSPITAL
ON JAN 29 2021 FOR IV
ANTIBIOTICS HE WAS
DISCHARGED ON JAN 30TH 2021
WITH ORAL ANTIBIOTICS
FLAGYL 500MG FOR 7 DAYS
AND CIPRO 500MG TWICE A
DAY FOR 7 DAYS.
(UPDATED
RECOVERED/RESOLVED DATE
TO 07/FEB/2021 WHICH IS THE
STOP DATE FOR HIS ORAL
ANTIBIOTICS).
A REQUEST FOR MEDICAL
RECORDS WAS SENT ON
JANUARY 31, 2021.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

AEID	
Adverse event	RIB PAIN RIGHT SIDE
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)	14 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (2)

Data signed: (b) (4) 26 Apr 2021 15:04:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

AEID	
Adverse event	OTALGIA
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)	14 FEB 2021
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	14 FEB 2021 00:00
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 (3)

Data signed: (b) (4) 26 Apr 2021 15:04:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

AEID

Adverse event

MYALGIA RIGHT SIDE OF BODY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 20:41:51

Generated On: 09 Jun 2021 16:06:57

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

Yes ☒

No ☐

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

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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) _____		
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 (2)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication COLACE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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) _____		
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 (3)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

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 (3)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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 (4)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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 (4)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication INFLUENA VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 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)		22 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 (6)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication FLAGYL

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	07 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication CIPRO

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 FEB 2021	
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"/>

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 3.375

Dose unit mg ☐
ug ☐
mL ☐
g ☒
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

100ML/HR, IVPB ONCE

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 (8)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 JAN 2021
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"/>

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 2

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 JAN 2021
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"/>

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication MILK OF MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

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

BID/PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 JAN 2021
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"/>

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication ROXICODONE

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

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

Q4HR/PRN

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 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 JAN 2021
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 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC

Dose per administration 325

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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 (13)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication FLEXERIL

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2004	
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 15

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2004	
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"/>

US3222554

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 21:27:45

Generated On: 09 Jun 2021 16:06:57

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) 05 Mar 2021 21:27:45

Generated On: 09 Jun 2021 16:06:57

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 JAN 2021	ABD/PELVIS W/CONT-CT SCAN	Adverse Event	

US3222554

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:06:57

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3222554

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:06:57

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

SAEID	USA-US104-2021-MRNA-1273-P301000006
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)	4

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

SAEID	USA-US104-2021-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	02/FEB/2021 12:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

SAEID	USA-US104-2021-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	04/MAR/2021 11:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

SAEID	USA-US104-2021-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	19/APR/2021 16:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 15:04:44

Generated On: 09 Jun 2021 16:06:57

SAEID	USA-US104-2021-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	19/APR/2021 16:35
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

US3222554 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222554

Form: Participant Creation

Generated On: 09 Jun 2021 16:06:57

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'US3222554'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 14:34:23

US3222554

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:29

US3222554

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '07 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 14:34:24

US3222554

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Clinic (Clinic)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	07 Sep 2020 15:09:29

US3222554

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'SCRN'	System	07 Sep 2020 15:09:29

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 14:34:25

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '69'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'YEARS'	System	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '69'	System	07 Sep 2020 15:09:42

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Male (M)'	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'I'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:57

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:17:54

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:42

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'Sep 2020'	System	07 Sep 2020 15:09:42

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '2020'	System	07 Sep 2020 15:09:42

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Amendment 3 (3)'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:42

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:42

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:42

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:42

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:42

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 14:34:24

US3222554

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:57

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '1'	System	07 Sep 2020 15:09:47

US3222554

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:06:57

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:47

US3222554

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:06:57

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	09 Sep 2020 13:19:02

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 13:23:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 13:23:46
Data point term sent to Coder	System	09 Sep 2020 13:23:26
User entered 'Vasectomy'	Albert Garcia (b) (4)	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'un UNK 1985'	Albert Garcia (b) (4)	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'un UNK 1985'	Albert Garcia (b) (4)	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'Jan 1985'	System	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '1985'	System	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'Jan 1985'	System	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '1985'	System	09 Sep 2020 13:22:28

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
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)	09 Sep 2020 13:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 13:28:39
Data point term sent to Coder	System	09 Sep 2020 13:26:32
User entered 'Hypertension'	Albert Garcia (b) (4)	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'un UNK 1995'	Albert Garcia (b) (4)	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'Jan 1995'	System	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '1995'	System	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered empty.	System	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered empty.	System	09 Sep 2020 13:25:44

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:43:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:43:32
Data point term sent to Coder	System	11 Sep 2020 11:42:54
User entered 'INSOMNIA'	Amber Vasquez (b) (4)	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'UN Jan 2005'	Amber Vasquez (b) (4)	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Amber Vasquez (b) (4)	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Amber Vasquez (b) (4)	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'Jan 2005'	System	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '2005'	System	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered empty.	System	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered empty.	System	11 Sep 2020 11:41:59

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:43:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:43:32
Data point term sent to Coder	System	11 Sep 2020 11:42:54
User entered 'HYPERLIPIDEMIA'	Amber Vasquez (b) (4)	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'UN UNK 2005'	(b) (4) Amber Vasquez (b) (4)	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Amber Vasquez (b) (4)	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	(b) (4) Amber Vasquez (b) (4)	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'Jan 2005'	System	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '2005'	System	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered empty.	System	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered empty.	System	11 Sep 2020 11:42:32

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 19:32:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 19:32:51
Data point term sent to Coder	System	14 Nov 2020 19:31:45
User entered 'CONSTIPATION'	Albert Garcia (b) (4)	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'UN UNK 2010'	Albert Garcia (b) (4)	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'Jan 2010'	System	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '2010'	System	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered empty.	System	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered empty.	System	14 Nov 2020 19:31:35

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	Albert Garcia (b) (4)	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '10:25'	Albert Garcia (b) (4)	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '7 Sep 2020 10:25'	System	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '167.6' cm	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:32:28
DataPoint set to visible.	(b) (4) System	07 Sep 2020 15:09:47

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '81.6' kg	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:32:28
DataPoint set to visible.	(b) (4) System	07 Sep 2020 15:09:47

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered '29.04973'	System	09 Sep 2020 13:32:28
DataPoint set to visible.	System	07 Sep 2020 15:09:47

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'kg/m2'	System	09 Sep 2020 13:32:28
DataPoint set to visible.	System	07 Sep 2020 15:09:47

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
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 08:02:38
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 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 16:48:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 16:48:39
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 18:27:31
User entered '36.1' C	Albert Garcia (b) (4) (b) (4)	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty; reason for change Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	06 Oct 2020 16:48:39
User entered 'Oral (Oral)'	(b) (4)	
	Albert Garcia (b) (4)	09 Sep 2020 13:32:28
	(b) (4)	

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:39
User entered '72'	Albert Garcia (b) (4)	09 Sep 2020 13:32:28
	(b) (4)	

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'bpm'	System	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:39
User entered '16'	Albert Garcia (b) (4)	09 Sep 2020 13:32:28
	(b) (4)	

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'breaths/min'	System	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:39
User entered '150'	Albert Garcia (b) (4)	09 Sep 2020 13:32:28
	(b) (4)	

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'mmHg'	System	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:39
User entered '94'	Albert Garcia (b) (4)	09 Sep 2020 13:32:28
	(b) (4)	

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User entered 'mmHg'	System	09 Sep 2020 13:32:28

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00

US3222554

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00

US3222554

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	09 Sep 2020 13:32:49

US3222554

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	Albert Garcia (b) (4)	09 Sep 2020 13:32:49

US3222554

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	09 Sep 2020 13:37:32

US3222554

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:37:32

US3222554

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'I'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

US3222554

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

US3222554

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

US3222554

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '0'	(b) (4) Albert Garcia (b) (4)	09 Sep 2020 13:37:32

US3222554

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:41:00
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:37:32

US3222554

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:59

US3222554

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:09:59

US3222554

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Clinic (Clinic)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	07 Sep 2020 15:09:59

US3222554

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'VISIT1'	System	07 Sep 2020 15:09:59

US3222554

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:57

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '07 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 14:44:19

US3222554

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:57

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '190174'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 14:44:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:57

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Sep 2020 14:44:19

US3222554

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:57

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:43:06

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:57

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:43:06

US3222554

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:57

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:43:06

US3222554

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:57

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:43:06

US3222554

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:57

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:43:06

US3222554

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:57

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	06 Oct 2020 16:48:51
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:34:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:34:37

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:57
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:45:38
	(b) (4)	

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:57
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:45:38
	(b) (4)	

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:57
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:45:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:57
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:45:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '10:30'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered '7 Sep 2020 10:30'	System	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '36.1' C	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '72'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'bpm'	System	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '16'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'breaths/min'	System	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '150'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'mmHg'	System	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '94'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'mmHg'	System	09 Sep 2020 13:45:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:57
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:45:38
	(b) (4)	

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:48:57
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:45:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '11:40'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered '7 Sep 2020 11:40'	System	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '36.3' C	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '76'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'bpm'	System	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '16'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'breaths/min'	System	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '140'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'mmHg'	System	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '80'	Albert Garcia (b) (4)	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'mmHg'	System	09 Sep 2020 13:45:38

US3222554

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	09 Sep 2020 13:45:48

US3222554

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	Albert Garcia (b) (4)	09 Sep 2020 13:45:48

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Crystal Paccione (b) (4)	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'MRNA-1273 OR PLACEBO'	System	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	Crystal Paccione (b) (4)	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '11:05'	(b) (4) Crystal Paccione (b) (4)	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered '7 Sep 2020 11:05'	System	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Left Arm (LEFT ARM)'	Crystal Paccione (b) (4)	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'ONCE'	System	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'INTRAMUSCULAR'	System	07 Sep 2020 15:10:36

US3222554

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	09 Sep 2020 13:46:05

US3222554

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	Albert Garcia (b) (4)	09 Sep 2020 13:46:05

US3222554

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '11:00'	Albert Garcia (b) (4)	09 Sep 2020 13:46:05

US3222554

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered '7 Sep 2020 11:00'	System	09 Sep 2020 13:46:05

US3222554

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:06:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Sep 2020'	Albert Garcia (b) (4)	09 Sep 2020 13:46:44

US3222554

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	09 Sep 2020 13:46:44

US3222554

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	09 Sep 2020 13:46:44

US3222554

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '11:01'	Albert Garcia (b) (4)	09 Sep 2020 13:46:44

US3222554

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered '7 Sep 2020 11:01'	System	09 Sep 2020 13:46:44

US3222554

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	09 Sep 2020 13:46:44

US3222554

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	09 Sep 2020 13:46:44

US3222554

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	09 Sep 2020 13:46:44

US3222554

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered empty.	System	09 Sep 2020 13:46:44

US3222554

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	09 Sep 2020 13:46:52

US3222554

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'I'	System	09 Sep 2020 13:46:52

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Sep 2020 11:25'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Sep 2020 13:55'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:54:09', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '0e08731b-1e47-4ea5-9f12-c28b60b5375e'	System	07 Sep 2020 23:55:07
User entered 'Yes (Y)'	System	07 Sep 2020 23:55:07

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:54:19', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '0e08731b-1e47-4ea5-9f12-c28b60b5375e'	System	07 Sep 2020 23:55:07
User entered '99.4'	System	07 Sep 2020 23:55:07

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:54:26', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '0e08731b-1e47-4ea5-9f12-c28b60b5375e'	System	07 Sep 2020 23:55:07
User entered 'No (N)'	System	07 Sep 2020 23:55:07

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:54:38', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '0e08731b-1e47-4ea5-9f12-c28b60b5375e'	System	07 Sep 2020 23:55:07
User entered '07 Sep 2020 19:54'	System	07 Sep 2020 23:55:07

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Sep 2020 14:50'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 2'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:06:44', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '58720704-ccc0-449e-8e02-63547d7bf503'	System	09 Sep 2020 06:07:03
User entered 'Yes (Y)'	System	09 Sep 2020 06:07:03

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:06:30', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '58720704-ccc0-449e-8e02-63547d7bf503'	System	09 Sep 2020 06:07:03
User entered '98.8'	System	09 Sep 2020 06:07:03

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:06:36', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '58720704-ccc0-449e-8e02-63547d7bf503'	System	09 Sep 2020 06:07:03
User entered 'No (N)'	System	09 Sep 2020 06:07:03

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:06:59', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '58720704-ccc0-449e-8e02-63547d7bf503'	System	09 Sep 2020 06:07:03
User entered '09 Sep 2020 02:06'	System	09 Sep 2020 06:07:03

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 3'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:51:50', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'c62cc7cf-0783-4252-8485-1e647e0b21f0'	System	10 Sep 2020 12:52:17
User entered 'Yes (Y)'	System	10 Sep 2020 12:52:17

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:51:59', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'c62cc7cf-0783-4252-8485-1e647e0b21f0'	System	10 Sep 2020 12:52:17
User entered '98.7'	System	10 Sep 2020 12:52:17

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:52:04', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'c62cc7cf-0783-4252-8485-1e647e0b21f0'	System	10 Sep 2020 12:52:17
User entered 'No (N)'	System	10 Sep 2020 12:52:17

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:52:15', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'c62cc7cf-0783-4252-8485-1e647e0b21f0'	System	10 Sep 2020 12:52:17
User entered '10 Sep 2020 08:52'	System	10 Sep 2020 12:52:17

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 4'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:36:18', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a8f1ebd0-1b1b-4160-83fb-b62b9d61e21f'	System	11 Sep 2020 03:36:42
User entered 'Yes (Y)'	System	11 Sep 2020 03:36:42

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:36:24', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a8f1ebd0-1b1b-4160-83fb-b62b9d61e21f'	System	11 Sep 2020 03:36:42
User entered '99.1'	System	11 Sep 2020 03:36:42

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:36:27', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a8f1ebd0-1b1b-4160-83fb-b62b9d61e21f'	System	11 Sep 2020 03:36:42
User entered 'No (N)'	System	11 Sep 2020 03:36:42

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:36:37', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a8f1ebd0-1b1b-4160-83fb-b62b9d61e21f'	System	11 Sep 2020 03:36:42
User entered '10 Sep 2020 23:36'	System	11 Sep 2020 03:36:42

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 5'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:42:21', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '21bc5fd3-9e35-4a03-a093-290ddf73c951'	System	12 Sep 2020 01:42:45
User entered 'Yes (Y)'	System	12 Sep 2020 01:42:45

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:42:25', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '21bc5fd3-9e35-4a03-a093-290ddf73c951'	System	12 Sep 2020 01:42:45
User entered '97.7'	System	12 Sep 2020 01:42:45

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:42:35', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '21bc5fd3-9e35-4a03-a093-290ddf73c951'	System	12 Sep 2020 01:42:45
User entered 'No (N)'	System	12 Sep 2020 01:42:45

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:42:41', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '21bc5fd3-9e35-4a03-a093-290ddf73c951'	System	12 Sep 2020 01:42:45
User entered '11 Sep 2020 21:42'	System	12 Sep 2020 01:42:45

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 6'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:30:45', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '41903267-ef3b-42e1-b888-d71289c545f9'	System	12 Sep 2020 22:31:36
User entered 'Yes (Y)'	System	12 Sep 2020 22:31:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:30:56', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '41903267-ef3b-42e1-b888-d71289c545f9'	System	12 Sep 2020 22:31:36
User entered '97.9'	System	12 Sep 2020 22:31:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:01', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '41903267-ef3b-42e1-b888-d71289c545f9'	System	12 Sep 2020 22:31:36
User entered 'No (N)'	System	12 Sep 2020 22:31:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:07', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '41903267-ef3b-42e1-b888-d71289c545f9'	System	12 Sep 2020 22:31:36
User entered '12 Sep 2020 18:31'	System	12 Sep 2020 22:31:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 7'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:06', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '0870d16f-44ad-496c-aa0f-f4e683a87148'	System	13 Sep 2020 19:44:23
User entered 'Yes (Y)'	System	13 Sep 2020 19:44:23

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '0870d16f-44ad-496c-aa0f-f4e683a87148'	System	13 Sep 2020 19:44:23
User entered '98.3'	System	13 Sep 2020 19:44:23

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:16', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '0870d16f-44ad-496c-aa0f-f4e683a87148'	System	13 Sep 2020 19:44:23
User entered 'No (N)'	System	13 Sep 2020 19:44:23

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:20', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '0870d16f-44ad-496c-aa0f-f4e683a87148'	System	13 Sep 2020 19:44:23
User entered '13 Sep 2020 15:44'	System	13 Sep 2020 19:44:23

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Sep 2020 11:25'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Sep 2020 13:55'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:54:59', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'dd376ed8-2890-469e-8767-e67bbd726cd5'	System	07 Sep 2020 23:55:35
User entered 'None (1)'	System	07 Sep 2020 23:55:35

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:55:04', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'dd376ed8-2890-469e-8767-e67bbd726cd5'	System	07 Sep 2020 23:55:35
User entered 'No (N)'	System	07 Sep 2020 23:55:35

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:55:09', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'dd376ed8-2890-469e-8767-e67bbd726cd5'	System	07 Sep 2020 23:55:35
User entered 'No (N)'	System	07 Sep 2020 23:55:35

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:55:21', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'dd376ed8-2890-469e-8767-e67bbd726cd5'	System	07 Sep 2020 23:55:35
User entered 'None (1)'	System	07 Sep 2020 23:55:35

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:55:32', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'dd376ed8-2890-469e-8767-e67bbd726cd5'	System	07 Sep 2020 23:55:35
User entered '07 Sep 2020 19:55'	System	07 Sep 2020 23:55:35

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Sep 2020 14:50'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 2'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:07:13', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '46d217d4-ed3c-4b9a-b2be-56748a867673'	System	09 Sep 2020 06:07:40
User entered 'None (1)'	System	09 Sep 2020 06:07:40

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:07:16', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '46d217d4-ed3c-4b9a-b2be-56748a867673'	System	09 Sep 2020 06:07:40
User entered 'No (N)'	System	09 Sep 2020 06:07:40

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:07:20', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '46d217d4-ed3c-4b9a-b2be-56748a867673'	System	09 Sep 2020 06:07:40
User entered 'No (N)'	System	09 Sep 2020 06:07:40

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:07:27', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '46d217d4-ed3c-4b9a-b2be-56748a867673'	System	09 Sep 2020 06:07:40
User entered 'None (1)'	System	09 Sep 2020 06:07:40

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:07:36', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '46d217d4-ed3c-4b9a-b2be-56748a867673'	System	09 Sep 2020 06:07:40
User entered '09 Sep 2020 02:07'	System	09 Sep 2020 06:07:40

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 3'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:52:25', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a5a458d0-c5c3-40a8-b09e-896ea32a2c46'	System	10 Sep 2020 12:52:54
User entered 'None (1)'	System	10 Sep 2020 12:52:54

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:52:30', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a5a458d0-c5c3-40a8-b09e-896ea32a2c46'	System	10 Sep 2020 12:52:54
User entered 'No (N)'	System	10 Sep 2020 12:52:54

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:52:33', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a5a458d0-c5c3-40a8-b09e-896ea32a2c46'	System	10 Sep 2020 12:52:54
User entered 'No (N)'	System	10 Sep 2020 12:52:54

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:52:43', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a5a458d0-c5c3-40a8-b09e-896ea32a2c46'	System	10 Sep 2020 12:52:54
User entered 'None (1)'	System	10 Sep 2020 12:52:54

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:52:49', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a5a458d0-c5c3-40a8-b09e-896ea32a2c46'	System	10 Sep 2020 12:52:54
User entered '10 Sep 2020 08:52'	System	10 Sep 2020 12:52:54

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 4'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:36:42', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '2d180cac-3562-445a-8411-1ebb2ec6d272'	System	11 Sep 2020 03:37:04
User entered 'None (1)'	System	11 Sep 2020 03:37:04

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:36:45', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '2d180cac-3562-445a-8411-1ebb2ec6d272'	System	11 Sep 2020 03:37:04
User entered 'No (N)'	System	11 Sep 2020 03:37:04

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:36:50', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '2d180cac-3562-445a-8411-1ebb2ec6d272'	System	11 Sep 2020 03:37:04
User entered 'No (N)'	System	11 Sep 2020 03:37:04

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:36:56', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '2d180cac-3562-445a-8411-1ebb2ec6d272'	System	11 Sep 2020 03:37:04
User entered 'None (1)'	System	11 Sep 2020 03:37:04

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:37:00', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '2d180cac-3562-445a-8411-1ebb2ec6d272'	System	11 Sep 2020 03:37:04
User entered '10 Sep 2020 23:37'	System	11 Sep 2020 03:37:04

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 5'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:42:50', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '15d47a7c-5479-4848-9e49-63f0a5842dd3'	System	12 Sep 2020 01:43:21
User entered 'None (1)'	System	12 Sep 2020 01:43:21

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:42:54', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '15d47a7c-5479-4848-9e49-63f0a5842dd3'	System	12 Sep 2020 01:43:21
User entered 'No (N)'	System	12 Sep 2020 01:43:21

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:42:58', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '15d47a7c-5479-4848-9e49-63f0a5842dd3'	System	12 Sep 2020 01:43:21
User entered 'No (N)'	System	12 Sep 2020 01:43:21

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:10', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '15d47a7c-5479-4848-9e49-63f0a5842dd3'	System	12 Sep 2020 01:43:21
User entered 'None (1)'	System	12 Sep 2020 01:43:21

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:15', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '15d47a7c-5479-4848-9e49-63f0a5842dd3'	System	12 Sep 2020 01:43:21
User entered '11 Sep 2020 21:43'	System	12 Sep 2020 01:43:21

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 6'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:16', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '10dffba6-6de1-486b-8fcf-869de59181bf'	System	12 Sep 2020 22:31:45
User entered 'None (1)'	System	12 Sep 2020 22:31:45

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:19', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '10dffba6-6de1-486b-8fcf-869de59181bf'	System	12 Sep 2020 22:31:45
User entered 'No (N)'	System	12 Sep 2020 22:31:45

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:23', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '10dffba6-6de1-486b-8fcf-869de59181bf'	System	12 Sep 2020 22:31:45
User entered 'No (N)'	System	12 Sep 2020 22:31:45

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:26', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '10dffba6-6de1-486b-8fcf-869de59181bf'	System	12 Sep 2020 22:31:45
User entered 'None (1)'	System	12 Sep 2020 22:31:45

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:29', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '10dffba6-6de1-486b-8fcf-869de59181bf'	System	12 Sep 2020 22:31:45
User entered '12 Sep 2020 18:31'	System	12 Sep 2020 22:31:45

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 7'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:27', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '3924d93c-fceb-4bd4-bb82-de602f6d14c7'	System	13 Sep 2020 19:44:48
User entered 'None (1)'	System	13 Sep 2020 19:44:48

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:30', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '3924d93c-fceb-4bd4-bb82-de602f6d14c7'	System	13 Sep 2020 19:44:48
User entered 'No (N)'	System	13 Sep 2020 19:44:48

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:34', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '3924d93c-fceb-4bd4-bb82-de602f6d14c7'	System	13 Sep 2020 19:44:48
User entered 'No (N)'	System	13 Sep 2020 19:44:48

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:40', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '3924d93c-fceb-4bd4-bb82-de602f6d14c7'	System	13 Sep 2020 19:44:48
User entered 'None (1)'	System	13 Sep 2020 19:44:48

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:43', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '3924d93c-fceb-4bd4-bb82-de602f6d14c7'	System	13 Sep 2020 19:44:48
User entered '13 Sep 2020 15:44'	System	13 Sep 2020 19:44:48

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Sep 2020 11:25'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Sep 2020 13:55'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:55:40', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27110861-6f8e-4781-84c2-1e3d8cba54b3'	System	07 Sep 2020 23:56:29
User entered 'None (0)'	System	07 Sep 2020 23:56:29

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:55:45', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27110861-6f8e-4781-84c2-1e3d8cba54b3'	System	07 Sep 2020 23:56:29
User entered 'None (0)'	System	07 Sep 2020 23:56:29

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:55:52', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27110861-6f8e-4781-84c2-1e3d8cba54b3'	System	07 Sep 2020 23:56:29
User entered 'None (0)'	System	07 Sep 2020 23:56:29

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:55:59', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27110861-6f8e-4781-84c2-1e3d8cba54b3'	System	07 Sep 2020 23:56:29
User entered 'None (0)'	System	07 Sep 2020 23:56:29

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:56:02', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27110861-6f8e-4781-84c2-1e3d8cba54b3'	System	07 Sep 2020 23:56:29
User entered 'None (0)'	System	07 Sep 2020 23:56:29

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:56:06', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27110861-6f8e-4781-84c2-1e3d8cba54b3'	System	07 Sep 2020 23:56:29
User entered 'None (0)'	System	07 Sep 2020 23:56:29

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:56:21', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27110861-6f8e-4781-84c2-1e3d8cba54b3'	System	07 Sep 2020 23:56:29
User entered 'No (N)'	System	07 Sep 2020 23:56:29

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-07T19:56:26', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27110861-6f8e-4781-84c2-1e3d8cba54b3'	System	07 Sep 2020 23:56:29
User entered '07 Sep 2020 19:56'	System	07 Sep 2020 23:56:29

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Sep 2020 14:50'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 2'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:07:44', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4b21bcc6-711f-4a94-a8c0-ed672a8f5dc2'	System	09 Sep 2020 06:08:14
User entered 'None (0)'	System	09 Sep 2020 06:08:14

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:07:48', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4b21bcc6-711f-4a94-a8c0-ed672a8f5dc2'	System	09 Sep 2020 06:08:14
User entered 'None (0)'	System	09 Sep 2020 06:08:14

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:07:52', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4b21bcc6-711f-4a94-a8c0-ed672a8f5dc2'	System	09 Sep 2020 06:08:14
User entered 'None (0)'	System	09 Sep 2020 06:08:14

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:07:55', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4b21bcc6-711f-4a94-a8c0-ed672a8f5dc2'	System	09 Sep 2020 06:08:14
User entered 'None (0)'	System	09 Sep 2020 06:08:14

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:08:00', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4b21bcc6-711f-4a94-a8c0-ed672a8f5dc2'	System	09 Sep 2020 06:08:14
User entered 'None (0)'	System	09 Sep 2020 06:08:14

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:08:03', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4b21bcc6-711f-4a94-a8c0-ed672a8f5dc2'	System	09 Sep 2020 06:08:14
User entered 'None (0)'	System	09 Sep 2020 06:08:14

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:08:09', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4b21bcc6-711f-4a94-a8c0-ed672a8f5dc2'	System	09 Sep 2020 06:08:14
User entered 'No (N)'	System	09 Sep 2020 06:08:14

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-09T02:08:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4b21bcc6-711f-4a94-a8c0-ed672a8f5dc2'	System	09 Sep 2020 06:08:14
User entered '09 Sep 2020 02:08'	System	09 Sep 2020 06:08:14

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 3'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:53:07', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43a37ce9-f83a-4de9-a788-92ad028a12d5'	System	10 Sep 2020 12:53:45
User entered 'None (0)'	System	10 Sep 2020 12:53:45

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:53:22', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43a37ce9-f83a-4de9-a788-92ad028a12d5'	System	10 Sep 2020 12:53:45
User entered 'None (0)'	System	10 Sep 2020 12:53:45

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:53:26', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43a37ce9-f83a-4de9-a788-92ad028a12d5'	System	10 Sep 2020 12:53:45
User entered 'None (0)'	System	10 Sep 2020 12:53:45

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:53:28', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43a37ce9-f83a-4de9-a788-92ad028a12d5'	System	10 Sep 2020 12:53:45
User entered 'None (0)'	System	10 Sep 2020 12:53:45

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:53:31', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43a37ce9-f83a-4de9-a788-92ad028a12d5'	System	10 Sep 2020 12:53:45
User entered 'None (0)'	System	10 Sep 2020 12:53:45

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:53:34', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43a37ce9-f83a-4de9-a788-92ad028a12d5'	System	10 Sep 2020 12:53:45
User entered 'None (0)'	System	10 Sep 2020 12:53:45

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:53:38', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43a37ce9-f83a-4de9-a788-92ad028a12d5'	System	10 Sep 2020 12:53:45
User entered 'No (N)'	System	10 Sep 2020 12:53:45

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T08:53:42', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43a37ce9-f83a-4de9-a788-92ad028a12d5'	System	10 Sep 2020 12:53:45
User entered '10 Sep 2020 08:53'	System	10 Sep 2020 12:53:45

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 4'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:37:06', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4be50501-b581-420c-a32b-0cf3fd567d8b'	System	11 Sep 2020 03:37:41
User entered 'None (0)'	System	11 Sep 2020 03:37:41

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:37:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4be50501-b581-420c-a32b-0cf3fd567d8b'	System	11 Sep 2020 03:37:41
User entered 'None (0)'	System	11 Sep 2020 03:37:41

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:37:16', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4be50501-b581-420c-a32b-0cf3fd567d8b'	System	11 Sep 2020 03:37:41
User entered 'None (0)'	System	11 Sep 2020 03:37:41

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:37:18', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4be50501-b581-420c-a32b-0cf3fd567d8b'	System	11 Sep 2020 03:37:41
User entered 'None (0)'	System	11 Sep 2020 03:37:41

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:37:21', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4be50501-b581-420c-a32b-0cf3fd567d8b'	System	11 Sep 2020 03:37:41
User entered 'None (0)'	System	11 Sep 2020 03:37:41

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:37:25', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4be50501-b581-420c-a32b-0cf3fd567d8b'	System	11 Sep 2020 03:37:41
User entered 'None (0)'	System	11 Sep 2020 03:37:41

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:37:30', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4be50501-b581-420c-a32b-0cf3fd567d8b'	System	11 Sep 2020 03:37:41
User entered 'No (N)'	System	11 Sep 2020 03:37:41

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-10T23:37:37', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '4be50501-b581-420c-a32b-0cf3fd567d8b'	System	11 Sep 2020 03:37:41
User entered '10 Sep 2020 23:37'	System	11 Sep 2020 03:37:41

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 5'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:21', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '9e3033c1-932f-4dd4-9362-a21cb941139a'	System	12 Sep 2020 01:43:53
User entered 'None (0)'	System	12 Sep 2020 01:43:53

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:23', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '9e3033c1-932f-4dd4-9362-a21cb941139a'	System	12 Sep 2020 01:43:53
User entered 'None (0)'	System	12 Sep 2020 01:43:53

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:26', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '9e3033c1-932f-4dd4-9362-a21cb941139a'	System	12 Sep 2020 01:43:53
User entered 'None (0)'	System	12 Sep 2020 01:43:53

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:27', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '9e3033c1-932f-4dd4-9362-a21cb941139a'	System	12 Sep 2020 01:43:53
User entered 'None (0)'	System	12 Sep 2020 01:43:53

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:30', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '9e3033c1-932f-4dd4-9362-a21cb941139a'	System	12 Sep 2020 01:43:53
User entered 'None (0)'	System	12 Sep 2020 01:43:53

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:37', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '9e3033c1-932f-4dd4-9362-a21cb941139a'	System	12 Sep 2020 01:43:53
User entered 'None (0)'	System	12 Sep 2020 01:43:53

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:45', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '9e3033c1-932f-4dd4-9362-a21cb941139a'	System	12 Sep 2020 01:43:53
User entered 'No (N)'	System	12 Sep 2020 01:43:53

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-11T21:43:48', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '9e3033c1-932f-4dd4-9362-a21cb941139a'	System	12 Sep 2020 01:43:53
User entered '11 Sep 2020 21:43'	System	12 Sep 2020 01:43:53

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 6'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:41', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '55c7a306-84b5-4649-b303-e7ebca987c69'	System	12 Sep 2020 22:32:20
User entered 'None (0)'	System	12 Sep 2020 22:32:20

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:46', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '55c7a306-84b5-4649-b303-e7ebca987c69'	System	12 Sep 2020 22:32:20
User entered 'None (0)'	System	12 Sep 2020 22:32:20

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:49', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '55c7a306-84b5-4649-b303-e7ebca987c69'	System	12 Sep 2020 22:32:20
User entered 'None (0)'	System	12 Sep 2020 22:32:20

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:31:54', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '55c7a306-84b5-4649-b303-e7ebca987c69'	System	12 Sep 2020 22:32:20
User entered 'None (0)'	System	12 Sep 2020 22:32:20

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:32:03', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '55c7a306-84b5-4649-b303-e7ebca987c69'	System	12 Sep 2020 22:32:20
User entered 'None (0)'	System	12 Sep 2020 22:32:20

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:32:08', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '55c7a306-84b5-4649-b303-e7ebca987c69'	System	12 Sep 2020 22:32:20
User entered 'None (0)'	System	12 Sep 2020 22:32:20

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:32:14', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '55c7a306-84b5-4649-b303-e7ebca987c69'	System	12 Sep 2020 22:32:20
User entered 'No (N)'	System	12 Sep 2020 22:32:20

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-12T18:32:17', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '55c7a306-84b5-4649-b303-e7ebca987c69'	System	12 Sep 2020 22:32:20
User entered '12 Sep 2020 18:32'	System	12 Sep 2020 22:32:20

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 7'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:51', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'd4098c65-3ca9-4c73-998c-15839386b0ea'	System	13 Sep 2020 19:45:46
User entered 'None (0)'	System	13 Sep 2020 19:45:46

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:44:56', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'd4098c65-3ca9-4c73-998c-15839386b0ea'	System	13 Sep 2020 19:45:46
User entered 'None (0)'	System	13 Sep 2020 19:45:46

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:45:02', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'd4098c65-3ca9-4c73-998c-15839386b0ea'	System	13 Sep 2020 19:45:46
User entered 'None (0)'	System	13 Sep 2020 19:45:46

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:45:10', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'd4098c65-3ca9-4c73-998c-15839386b0ea'	System	13 Sep 2020 19:45:46
User entered 'None (0)'	System	13 Sep 2020 19:45:46

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:45:15', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'd4098c65-3ca9-4c73-998c-15839386b0ea'	System	13 Sep 2020 19:45:46
User entered 'None (0)'	System	13 Sep 2020 19:45:46

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:45:30', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'd4098c65-3ca9-4c73-998c-15839386b0ea'	System	13 Sep 2020 19:45:46
User entered 'None (0)'	System	13 Sep 2020 19:45:46

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:45:39', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'd4098c65-3ca9-4c73-998c-15839386b0ea'	System	13 Sep 2020 19:45:46
User entered 'No (N)'	System	13 Sep 2020 19:45:46

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-09-13T15:45:43', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'd4098c65-3ca9-4c73-998c-15839386b0ea'	System	13 Sep 2020 19:45:46
User entered '13 Sep 2020 15:45'	System	13 Sep 2020 19:45:46

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 15:10:36

US3222554

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:03:14

US3222554

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '14 Sep 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	04 Oct 2020 17:03:14

US3222554

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	04 Oct 2020 17:03:14

US3222554

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:03:14

US3222554

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:03:20

US3222554

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'I'	System	04 Oct 2020 17:03:20

US3222554

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:03:34

US3222554

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '21 Sep 2020'	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:03:34

US3222554

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	04 Oct 2020 17:03:34

US3222554

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:03:34

US3222554

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:03:39

US3222554

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'I'	System	04 Oct 2020 17:03:39

US3222554

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:03:58

US3222554

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	04 Oct 2020 17:04:33
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	04 Oct 2020 17:04:33
User entered '28 Sep 2020' reason for change: Data Entry Error	Crystal Paccione (b) (4)	04 Oct 2020 17:04:33
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Oct 2020 17:03:58
User entered '21 Sep 2020'	Crystal Paccione (b) (4)	04 Oct 2020 17:03:58
	(b) (4)	

US3222554

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	04 Oct 2020 17:03:58

US3222554

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:03:58

US3222554

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	04 Oct 2020 17:04:39

US3222554

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'I'	System	04 Oct 2020 17:04:39

US3222554

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 12:35:01

US3222554

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '7 Oct 2020' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	07 Oct 2020 16:28:37
User entered '5 Oct 2020'	Albert Garcia (b) (4)	07 Oct 2020 12:35:01

US3222554

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	07 Oct 2020 12:35:01

US3222554

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'VISIT2'	System	07 Oct 2020 12:35:01

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	08 Oct 2020 11:30:10
User entered '7 Oct 2020' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	08 Oct 2020 11:30:10
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 16:28:37
User entered '5 Oct 2020'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '11:01' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:10
User entered '10:57'	(b) (4)	
	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered '7 Oct 2020 11:01'	System	08 Oct 2020 11:30:10
User entered '5 Oct 2020 10:57'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '37.3' C reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:10
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	07 Oct 2020 12:37:19
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	07 Oct 2020 12:37:19
User entered '98.5' F reason for change: Data Entry Error	Albert Garcia (b) (4)	07 Oct 2020 12:37:19
	(b) (4)	
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	07 Oct 2020 12:36:52
User entered '98.5' C	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '71' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:10
User entered '86'	(b) (4)	
	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'bpm'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '17' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:10
User entered '12'	(b) (4)	
	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'breaths/min'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '140' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:10
User entered '115'	(b) (4)	
	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'mmHg'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '78' reason for change: Data Entry Error	Albert Garcia (b) (4)	08 Oct 2020 11:30:10
User entered '97'	Albert Garcia (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'mmHg'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	08 Oct 2020 11:30:50
User entered '7 Oct 2020' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	08 Oct 2020 11:30:50
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 16:28:37
User entered '5 Oct 2020'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	08 Oct 2020 11:30:50
User entered '12:57' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	08 Oct 2020 11:30:50
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	08 Oct 2020 11:30:10
User entered '12:14'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered '7 Oct 2020 12:57'	System	08 Oct 2020 11:30:50
User entered '5 Oct 2020 12:14'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '37.1' C reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:50
User entered '36.8' C	(b) (4)	
	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '70' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:50
User entered '64'	(b) (4)	
	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'bpm'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '17' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:50
User entered '14'	(b) (4)	
	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'breaths/min'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '139' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:50
User entered '134'	(b) (4)	
	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'mmHg'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '86' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	08 Oct 2020 11:30:50
User entered '81'	(b) (4)	
	Albert Garcia (b) (4)	07 Oct 2020 12:36:52
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'mmHg'	System	07 Oct 2020 12:36:52

US3222554

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 12:41:54

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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System (b) (4)	16 Oct 2020 16:24:12
User entered '7 Oct 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Oct 2020 16:24:12
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System (b) (4)	07 Oct 2020 16:28:37
User entered '5 Oct 2020'	Albert Garcia (b) (4)	07 Oct 2020 12:41:54

US3222554

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 12:42:26

US3222554

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 12:42:26

US3222554

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 12:42:26

US3222554

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 12:42:26

US3222554

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	07 Oct 2020 16:29:02
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	07 Oct 2020 16:29:02
User entered '7 Oct 2020' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	07 Oct 2020 16:29:02
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '5 Oct 2020'	System	07 Oct 2020 16:28:37
	Albert Garcia (b) (4)	07 Oct 2020 12:42:26
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '12:15' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	07 Oct 2020 16:29:02
User entered '11:38'	Albert Garcia (b) (4)	07 Oct 2020 12:42:26

US3222554

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered '7 Oct 2020 12:15'	System	07 Oct 2020 16:29:02
User entered '5 Oct 2020 11:38'	System	07 Oct 2020 12:42:26

US3222554

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Left Arm (LEFT ARM)'	Albert Garcia (b) (4)	07 Oct 2020 12:42:26

US3222554

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'ONCE'	System	07 Oct 2020 12:42:26

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 12:42:26

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 12:42:42

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	08 Oct 2020 11:27:54
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	08 Oct 2020 11:27:54
User entered '7 Oct 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	08 Oct 2020 11:27:54
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	07 Oct 2020 16:28:37
User entered '5 Oct 2020'	System	07 Oct 2020 12:42:42
	Albert Garcia (b) (4)	
	(b) (4)	

US3222554

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '11:26' reason for change: Data Entry Error	Albert Garcia (b) (4)	08 Oct 2020 11:29:00
User entered '11:15'	Albert Garcia (b) (4)	07 Oct 2020 12:42:42

US3222554

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered '7 Oct 2020 11:26'	System	08 Oct 2020 11:29:00
User entered '7 Oct 2020 11:15'	System	08 Oct 2020 11:27:54
User entered '5 Oct 2020 11:15'	System	07 Oct 2020 12:42:42

US3222554

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:06:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	08 Oct 2020 11:28:11
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	08 Oct 2020 11:28:11
User entered '7 Oct 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	08 Oct 2020 11:28:11
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	07 Oct 2020 16:28:37
User entered '5 Oct 2020'	System	07 Oct 2020 12:43:30
	Albert Garcia (b) (4)	
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 12:43:30

US3222554

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 12:43:30

US3222554

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	08 Oct 2020 11:28:37
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	08 Oct 2020 11:28:37
User entered '11:30' reason for change: Data Entry Error	Albert Garcia (b) (4)	08 Oct 2020 11:28:37
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	07 Oct 2020 12:43:30
User entered empty.	System	07 Oct 2020 12:43:30
	Albert Garcia (b) (4)	07 Oct 2020 12:43:30
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered '7 Oct 2020 11:30'	System	08 Oct 2020 11:28:37
User entered empty.	System	07 Oct 2020 12:43:30

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:57

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 12:43:30

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'No (N)'	Albert Garcia (b) (4)	07 Oct 2020 12:43:30

US3222554

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 12:43:30

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered empty.	System	07 Oct 2020 12:43:30

US3222554

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 12:43:45

US3222554

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'I'	System	07 Oct 2020 12:43:45

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:44:09', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '3ec94ee1-fe2e-489f-aada-a05938121a64'	System	07 Oct 2020 16:44:37
User entered 'Yes (Y)'	System	07 Oct 2020 16:44:37

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:44:19', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '3ec94ee1-fe2e-489f-aada-a05938121a64'	System	07 Oct 2020 16:44:37
User entered '98.8'	System	07 Oct 2020 16:44:37

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:44:24', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '3ec94ee1-fe2e-489f-aada-a05938121a64'	System	07 Oct 2020 16:44:37
User entered 'No (N)'	System	07 Oct 2020 16:44:37

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:44:34', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '3ec94ee1-fe2e-489f-aada-a05938121a64'	System	07 Oct 2020 16:44:37
User entered '07 Oct 2020 12:44'	System	07 Oct 2020 16:44:37

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Oct 2020 12:35'	System	07 Oct 2020 16:29:02
User entered '05 Oct 2020 11:58'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Oct 2020 15:05'	System	07 Oct 2020 16:29:02
User entered '05 Oct 2020 14:28'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:42:57', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '1fb7c43a-e4b5-4e11-a289-3fbfc1ff8510'	System	08 Oct 2020 12:43:18
User entered 'Yes (Y)'	System	08 Oct 2020 12:43:18

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:02', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '1fb7c43a-e4b5-4e11-a289-3fbfc1ff8510'	System	08 Oct 2020 12:43:18
User entered '98.8'	System	08 Oct 2020 12:43:18

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:06', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '1fb7c43a-e4b5-4e11-a289-3fbfc1ff8510'	System	08 Oct 2020 12:43:18
User entered 'No (N)'	System	08 Oct 2020 12:43:18

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '1fb7c43a-e4b5-4e11-a289-3fbfc1ff8510'	System	08 Oct 2020 12:43:18
User entered '08 Oct 2020 08:43'	System	08 Oct 2020 12:43:18

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Oct 2020 16:00'	System	07 Oct 2020 16:29:02
User entered '05 Oct 2020 15:23'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '06 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 2'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:21:33', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7f3eb5b0-2ebf-4ae5-99a6-e7260ff16a73'	System	09 Oct 2020 03:21:49
User entered 'Yes (Y)'	System	09 Oct 2020 03:21:49

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:21:38', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7f3eb5b0-2ebf-4ae5-99a6-e7260ff16a73'	System	09 Oct 2020 03:21:49
User entered '97.8'	System	09 Oct 2020 03:21:49

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:21:43', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7f3eb5b0-2ebf-4ae5-99a6-e7260ff16a73'	System	09 Oct 2020 03:21:49
User entered 'No (N)'	System	09 Oct 2020 03:21:49

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:21:46', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7f3eb5b0-2ebf-4ae5-99a6-e7260ff16a73'	System	09 Oct 2020 03:21:49
User entered '08 Oct 2020 23:21'	System	09 Oct 2020 03:21:49

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '06 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '07 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 3'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:02:47', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43219475-d724-4d5e-9094-122778afb69a'	System	10 Oct 2020 12:03:05
User entered 'Yes (Y)'	System	10 Oct 2020 12:03:05

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:02:52', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43219475-d724-4d5e-9094-122778afb69a' User entered '98.3'	System	10 Oct 2020 12:03:05
	System	10 Oct 2020 12:03:05

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:02:55', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43219475-d724-4d5e-9094-122778afb69a'	System	10 Oct 2020 12:03:05
User entered 'No (N)'	System	10 Oct 2020 12:03:05

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:00', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '43219475-d724-4d5e-9094-122778afb69a'	System	10 Oct 2020 12:03:05
User entered '10 Oct 2020 08:03'	System	10 Oct 2020 12:03:05

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 4'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:21:44', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27951412-5ffb-4b74-a300-f73a26d7f62b'	System	10 Oct 2020 23:22:01
User entered 'Yes (Y)'	System	10 Oct 2020 23:22:01

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:21:49', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27951412-5ffb-4b74-a300-f73a26d7f62b'	System	10 Oct 2020 23:22:01
User entered '98.3'	System	10 Oct 2020 23:22:01

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:21:52', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27951412-5ffb-4b74-a300-f73a26d7f62b'	System	10 Oct 2020 23:22:01
User entered 'No (N)'	System	10 Oct 2020 23:22:01

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:21:58', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '27951412-5ffb-4b74-a300-f73a26d7f62b'	System	10 Oct 2020 23:22:01
User entered '10 Oct 2020 19:21'	System	10 Oct 2020 23:22:01

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 5'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:21:27', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'fd58f05c-4b11-44cd-8353-59d2b7fbb14c'	System	11 Oct 2020 17:21:40
User entered 'Yes (Y)'	System	11 Oct 2020 17:21:40

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:21:32', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'fd58f05c-4b11-44cd-8353-59d2b7fbb14c'	System	11 Oct 2020 17:21:40
User entered '97.6'	System	11 Oct 2020 17:21:40

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:21:36', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'fd58f05c-4b11-44cd-8353-59d2b7fbb14c'	System	11 Oct 2020 17:21:40
User entered 'No (N)'	System	11 Oct 2020 17:21:40

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:21:38', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'fd58f05c-4b11-44cd-8353-59d2b7fbb14c'	System	11 Oct 2020 17:21:40
User entered '11 Oct 2020 13:21'	System	11 Oct 2020 17:21:40

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 6'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:11:25', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '2c1211c0-0d7e-4b14-95bf-d19d7c47d4d0'	System	12 Oct 2020 18:11:46
User entered 'Yes (Y)'	System	12 Oct 2020 18:11:46

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:11:34', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '2c1211c0-0d7e-4b14-95bf-d19d7c47d4d0'	System	12 Oct 2020 18:11:46
User entered '98.3'	System	12 Oct 2020 18:11:46

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:11:40', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '2c1211c0-0d7e-4b14-95bf-d19d7c47d4d0'	System	12 Oct 2020 18:11:46
User entered 'No (N)'	System	12 Oct 2020 18:11:46

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:11:44', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '2c1211c0-0d7e-4b14-95bf-d19d7c47d4d0'	System	12 Oct 2020 18:11:46
User entered '12 Oct 2020 14:11'	System	12 Oct 2020 18:11:46

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 7'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:29:31', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '34313d31-fb25-4d6c-820a-668a8822725b'	System	14 Oct 2020 13:29:49
User entered 'Yes (Y)'	System	14 Oct 2020 13:29:49

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:29:37', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '34313d31-fb25-4d6c-820a-668a8822725b' User entered '97.7'	System	14 Oct 2020 13:29:49
	System	14 Oct 2020 13:29:49

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:29:42', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '34313d31-fb25-4d6c-820a-668a8822725b'	System	14 Oct 2020 13:29:49
User entered 'No (N)'	System	14 Oct 2020 13:29:49

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:29:46', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '34313d31-fb25-4d6c-820a-668a8822725b'	System	14 Oct 2020 13:29:49
User entered '14 Oct 2020 09:29'	System	14 Oct 2020 13:29:49

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:44:51', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ddb28636-af09-40dd-824c-ed439aba2c06'	System	07 Oct 2020 16:45:40
User entered 'None (1)'	System	07 Oct 2020 16:45:40

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:45:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ddb28636-af09-40dd-824c-ed439aba2c06'	System	07 Oct 2020 16:45:40
User entered 'No (N)'	System	07 Oct 2020 16:45:40

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:45:16', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ddb28636-af09-40dd-824c-ed439aba2c06'	System	07 Oct 2020 16:45:40
User entered 'No (N)'	System	07 Oct 2020 16:45:40

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:45:32', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ddb28636-af09-40dd-824c-ed439aba2c06'	System	07 Oct 2020 16:45:40
User entered 'None (1)'	System	07 Oct 2020 16:45:40

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:45:35', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ddb28636-af09-40dd-824c-ed439aba2c06'	System	07 Oct 2020 16:45:40
User entered '07 Oct 2020 12:45'	System	07 Oct 2020 16:45:40

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Oct 2020 12:35'	System	07 Oct 2020 16:29:02
User entered '05 Oct 2020 11:58'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Oct 2020 15:05'	System	07 Oct 2020 16:29:02
User entered '05 Oct 2020 14:28'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:20', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'c60e5427-ed08-410c-9281-40ebdc22f14a'	System	08 Oct 2020 12:43:52
User entered 'None (1)'	System	08 Oct 2020 12:43:52

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:29', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'c60e5427-ed08-410c-9281-40ebdc22f14a'	System	08 Oct 2020 12:43:52
User entered 'No (N)'	System	08 Oct 2020 12:43:52

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:36', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'c60e5427-ed08-410c-9281-40ebdc22f14a'	System	08 Oct 2020 12:43:52
User entered 'No (N)'	System	08 Oct 2020 12:43:52

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:43', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'c60e5427-ed08-410c-9281-40ebdc22f14a'	System	08 Oct 2020 12:43:52
User entered 'None (1)'	System	08 Oct 2020 12:43:52

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:46', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'c60e5427-ed08-410c-9281-40ebdc22f14a'	System	08 Oct 2020 12:43:52
User entered '08 Oct 2020 08:43'	System	08 Oct 2020 12:43:52

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Oct 2020 16:00'	System	07 Oct 2020 16:29:02
User entered '05 Oct 2020 15:23'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '06 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 2'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:21:51', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'b34d6126-2c31-445d-b12e-9b4d3b8d4370'	System	09 Oct 2020 03:22:15
User entered 'None (1)'	System	09 Oct 2020 03:22:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:21:54', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'b34d6126-2c31-445d-b12e-9b4d3b8d4370'	System	09 Oct 2020 03:22:15
User entered 'No (N)'	System	09 Oct 2020 03:22:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:21:57', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'b34d6126-2c31-445d-b12e-9b4d3b8d4370'	System	09 Oct 2020 03:22:15
User entered 'No (N)'	System	09 Oct 2020 03:22:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:07', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'b34d6126-2c31-445d-b12e-9b4d3b8d4370'	System	09 Oct 2020 03:22:15
User entered 'None (1)'	System	09 Oct 2020 03:22:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:10', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'b34d6126-2c31-445d-b12e-9b4d3b8d4370'	System	09 Oct 2020 03:22:15
User entered '08 Oct 2020 23:22'	System	09 Oct 2020 03:22:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '06 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '07 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 3'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:05', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '76d7be48-a559-411b-810e-6b0b494cc472'	System	10 Oct 2020 12:03:23
User entered 'None (1)'	System	10 Oct 2020 12:03:23

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:08', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '76d7be48-a559-411b-810e-6b0b494cc472'	System	10 Oct 2020 12:03:23
User entered 'No (N)'	System	10 Oct 2020 12:03:23

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '76d7be48-a559-411b-810e-6b0b494cc472'	System	10 Oct 2020 12:03:23
User entered 'No (N)'	System	10 Oct 2020 12:03:23

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:17', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '76d7be48-a559-411b-810e-6b0b494cc472'	System	10 Oct 2020 12:03:23
User entered 'None (1)'	System	10 Oct 2020 12:03:23

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:20', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '76d7be48-a559-411b-810e-6b0b494cc472'	System	10 Oct 2020 12:03:23
User entered '10 Oct 2020 08:03'	System	10 Oct 2020 12:03:23

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 4'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:22:20', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '62bdc6de-bd45-4fce-b587-1f4e27f5e6a7'	System	10 Oct 2020 23:22:41
User entered 'None (1)'	System	10 Oct 2020 23:22:41

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:22:23', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '62bdc6de-bd45-4fce-b587-1f4e27f5e6a7'	System	10 Oct 2020 23:22:41
User entered 'No (N)'	System	10 Oct 2020 23:22:41

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:22:27', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '62bdc6de-bd45-4fce-b587-1f4e27f5e6a7'	System	10 Oct 2020 23:22:41
User entered 'No (N)'	System	10 Oct 2020 23:22:41

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:22:32', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '62bdc6de-bd45-4fce-b587-1f4e27f5e6a7'	System	10 Oct 2020 23:22:41
User entered 'None (1)'	System	10 Oct 2020 23:22:41

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:22:35', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '62bdc6de-bd45-4fce-b587-1f4e27f5e6a7'	System	10 Oct 2020 23:22:41
User entered '10 Oct 2020 19:22'	System	10 Oct 2020 23:22:41

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 5'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:21:43', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '144041b3-358b-40f3-b6ba-e4127c655345'	System	11 Oct 2020 17:22:04
User entered 'None (1)'	System	11 Oct 2020 17:22:04

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:21:46', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '144041b3-358b-40f3-b6ba-e4127c655345'	System	11 Oct 2020 17:22:04
User entered 'No (N)'	System	11 Oct 2020 17:22:04

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:21:49', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '144041b3-358b-40f3-b6ba-e4127c655345'	System	11 Oct 2020 17:22:04
User entered 'No (N)'	System	11 Oct 2020 17:22:04

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:21:54', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '144041b3-358b-40f3-b6ba-e4127c655345'	System	11 Oct 2020 17:22:04
User entered 'None (1)'	System	11 Oct 2020 17:22:04

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:21:57', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '144041b3-358b-40f3-b6ba-e4127c655345'	System	11 Oct 2020 17:22:04
User entered '11 Oct 2020 13:21'	System	11 Oct 2020 17:22:04

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 6'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:11:53', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '63c1e347-a658-4f02-89b7-279dcb0e7d1a'	System	12 Oct 2020 18:12:15
User entered 'None (1)'	System	12 Oct 2020 18:12:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:11:56', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '63c1e347-a658-4f02-89b7-279dcb0e7d1a'	System	12 Oct 2020 18:12:15
User entered 'No (N)'	System	12 Oct 2020 18:12:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:11:59', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '63c1e347-a658-4f02-89b7-279dcb0e7d1a'	System	12 Oct 2020 18:12:15
User entered 'No (N)'	System	12 Oct 2020 18:12:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:09', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '63c1e347-a658-4f02-89b7-279dcb0e7d1a'	System	12 Oct 2020 18:12:15
User entered 'None (1)'	System	12 Oct 2020 18:12:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '63c1e347-a658-4f02-89b7-279dcb0e7d1a'	System	12 Oct 2020 18:12:15
User entered '12 Oct 2020 14:12'	System	12 Oct 2020 18:12:15

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 7'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:29:51', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'db3fc743-102c-4410-a63b-a9dca545ce2e'	System	14 Oct 2020 13:30:10
User entered 'None (1)'	System	14 Oct 2020 13:30:10

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:29:56', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'db3fc743-102c-4410-a63b-a9dca545ce2e'	System	14 Oct 2020 13:30:10
User entered 'No (N)'	System	14 Oct 2020 13:30:10

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:29:59', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'db3fc743-102c-4410-a63b-a9dca545ce2e'	System	14 Oct 2020 13:30:10
User entered 'No (N)'	System	14 Oct 2020 13:30:10

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:02', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'db3fc743-102c-4410-a63b-a9dca545ce2e'	System	14 Oct 2020 13:30:10
User entered 'None (1)'	System	14 Oct 2020 13:30:10

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:05', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'db3fc743-102c-4410-a63b-a9dca545ce2e'	System	14 Oct 2020 13:30:10
User entered '14 Oct 2020 09:30'	System	14 Oct 2020 13:30:10

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:45:43', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '79bb9057-1757-4521-928d-6f4c2b67e5fb'	System	07 Oct 2020 16:46:20
User entered 'None (0)'	System	07 Oct 2020 16:46:20

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:45:48', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '79bb9057-1757-4521-928d-6f4c2b67e5fb'	System	07 Oct 2020 16:46:20
User entered 'None (0)'	System	07 Oct 2020 16:46:20

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:45:54', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '79bb9057-1757-4521-928d-6f4c2b67e5fb'	System	07 Oct 2020 16:46:20
User entered 'None (0)'	System	07 Oct 2020 16:46:20

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:45:58', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '79bb9057-1757-4521-928d-6f4c2b67e5fb'	System	07 Oct 2020 16:46:20
User entered 'None (0)'	System	07 Oct 2020 16:46:20

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:46:03', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '79bb9057-1757-4521-928d-6f4c2b67e5fb'	System	07 Oct 2020 16:46:20
User entered 'None (0)'	System	07 Oct 2020 16:46:20

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:46:05', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '79bb9057-1757-4521-928d-6f4c2b67e5fb'	System	07 Oct 2020 16:46:20
User entered 'None (0)'	System	07 Oct 2020 16:46:20

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:46:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '79bb9057-1757-4521-928d-6f4c2b67e5fb'	System	07 Oct 2020 16:46:20
User entered 'No (N)'	System	07 Oct 2020 16:46:20

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-07T12:46:16', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '79bb9057-1757-4521-928d-6f4c2b67e5fb'	System	07 Oct 2020 16:46:20
User entered '07 Oct 2020 12:46'	System	07 Oct 2020 16:46:20

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Oct 2020 12:35'	System	07 Oct 2020 16:29:02
User entered '05 Oct 2020 11:58'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Oct 2020 15:05'	System	07 Oct 2020 16:29:02
User entered '05 Oct 2020 14:28'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:54', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '5b3857a1-daef-41b9-a072-0f446e18bdab'	System	08 Oct 2020 12:44:30
User entered 'None (0)'	System	08 Oct 2020 12:44:30

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:43:56', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '5b3857a1-daef-41b9-a072-0f446e18bdab'	System	08 Oct 2020 12:44:30
User entered 'None (0)'	System	08 Oct 2020 12:44:30

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:44:04', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '5b3857a1-daef-41b9-a072-0f446e18bdab'	System	08 Oct 2020 12:44:30
User entered 'None (0)'	System	08 Oct 2020 12:44:30

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:44:08', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '5b3857a1-daef-41b9-a072-0f446e18bdab'	System	08 Oct 2020 12:44:30
User entered 'None (0)'	System	08 Oct 2020 12:44:30

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:44:14', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '5b3857a1-daef-41b9-a072-0f446e18bdab'	System	08 Oct 2020 12:44:30
User entered 'None (0)'	System	08 Oct 2020 12:44:30

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:44:20', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '5b3857a1-daef-41b9-a072-0f446e18bdab'	System	08 Oct 2020 12:44:30
User entered 'None (0)'	System	08 Oct 2020 12:44:30

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:44:25', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '5b3857a1-daef-41b9-a072-0f446e18bdab'	System	08 Oct 2020 12:44:30
User entered 'No (N)'	System	08 Oct 2020 12:44:30

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T08:44:27', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '5b3857a1-daef-41b9-a072-0f446e18bdab'	System	08 Oct 2020 12:44:30
User entered '08 Oct 2020 08:44'	System	08 Oct 2020 12:44:30

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '07 Oct 2020 16:00'	System	07 Oct 2020 16:29:02
User entered '05 Oct 2020 15:23'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '06 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 2'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:15', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '98f5a3ef-7a21-4b0b-b604-4ba13d0e01dd'	System	09 Oct 2020 03:22:43
User entered 'None (0)'	System	09 Oct 2020 03:22:43

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:17', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '98f5a3ef-7a21-4b0b-b604-4ba13d0e01dd'	System	09 Oct 2020 03:22:43
User entered 'None (0)'	System	09 Oct 2020 03:22:43

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:20', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '98f5a3ef-7a21-4b0b-b604-4ba13d0e01dd'	System	09 Oct 2020 03:22:43
User entered 'None (0)'	System	09 Oct 2020 03:22:43

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:22', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '98f5a3ef-7a21-4b0b-b604-4ba13d0e01dd'	System	09 Oct 2020 03:22:43
User entered 'None (0)'	System	09 Oct 2020 03:22:43

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:25', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '98f5a3ef-7a21-4b0b-b604-4ba13d0e01dd'	System	09 Oct 2020 03:22:43
User entered 'None (0)'	System	09 Oct 2020 03:22:43

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:28', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '98f5a3ef-7a21-4b0b-b604-4ba13d0e01dd'	System	09 Oct 2020 03:22:43
User entered 'None (0)'	System	09 Oct 2020 03:22:43

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:35', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '98f5a3ef-7a21-4b0b-b604-4ba13d0e01dd'	System	09 Oct 2020 03:22:43
User entered 'No (N)'	System	09 Oct 2020 03:22:43

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-08T23:22:38', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '98f5a3ef-7a21-4b0b-b604-4ba13d0e01dd'	System	09 Oct 2020 03:22:43
User entered '08 Oct 2020 23:22'	System	09 Oct 2020 03:22:43

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '06 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '07 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 3'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:25', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a29e2038-8f26-4645-93c8-626ecca78b94'	System	10 Oct 2020 12:03:54
User entered 'None (0)'	System	10 Oct 2020 12:03:54

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:28', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a29e2038-8f26-4645-93c8-626ecca78b94'	System	10 Oct 2020 12:03:54
User entered 'None (0)'	System	10 Oct 2020 12:03:54

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:31', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a29e2038-8f26-4645-93c8-626ecca78b94'	System	10 Oct 2020 12:03:54
User entered 'None (0)'	System	10 Oct 2020 12:03:54

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:34', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a29e2038-8f26-4645-93c8-626ecca78b94'	System	10 Oct 2020 12:03:54
User entered 'None (0)'	System	10 Oct 2020 12:03:54

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:37', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a29e2038-8f26-4645-93c8-626ecca78b94'	System	10 Oct 2020 12:03:54
User entered 'None (0)'	System	10 Oct 2020 12:03:54

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:40', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a29e2038-8f26-4645-93c8-626ecca78b94'	System	10 Oct 2020 12:03:54
User entered 'None (0)'	System	10 Oct 2020 12:03:54

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:44', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a29e2038-8f26-4645-93c8-626ecca78b94'	System	10 Oct 2020 12:03:54
User entered 'No (N)'	System	10 Oct 2020 12:03:54

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T08:03:48', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'a29e2038-8f26-4645-93c8-626ecca78b94'	System	10 Oct 2020 12:03:54
User entered '10 Oct 2020 08:03'	System	10 Oct 2020 12:03:54

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 4'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:22:41', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '71e6a465-ab2d-41ca-b288-03e34f924f0d'	System	10 Oct 2020 23:23:16
User entered 'None (0)'	System	10 Oct 2020 23:23:16

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:22:50', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '71e6a465-ab2d-41ca-b288-03e34f924f0d'	System	10 Oct 2020 23:23:16
User entered 'None (0)'	System	10 Oct 2020 23:23:16

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:22:53', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '71e6a465-ab2d-41ca-b288-03e34f924f0d'	System	10 Oct 2020 23:23:16
User entered 'None (0)'	System	10 Oct 2020 23:23:16

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:22:57', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '71e6a465-ab2d-41ca-b288-03e34f924f0d'	System	10 Oct 2020 23:23:16
User entered 'None (0)'	System	10 Oct 2020 23:23:16

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:23:00', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '71e6a465-ab2d-41ca-b288-03e34f924f0d'	System	10 Oct 2020 23:23:16
User entered 'None (0)'	System	10 Oct 2020 23:23:16

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:23:03', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '71e6a465-ab2d-41ca-b288-03e34f924f0d'	System	10 Oct 2020 23:23:16
User entered 'None (0)'	System	10 Oct 2020 23:23:16

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:23:07', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '71e6a465-ab2d-41ca-b288-03e34f924f0d'	System	10 Oct 2020 23:23:16
User entered 'No (N)'	System	10 Oct 2020 23:23:16

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-10T19:23:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '71e6a465-ab2d-41ca-b288-03e34f924f0d'	System	10 Oct 2020 23:23:16
User entered '10 Oct 2020 19:23'	System	10 Oct 2020 23:23:16

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 5'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:22:03', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'e325d46d-b737-49bb-a43f-22513f047230'	System	11 Oct 2020 17:22:38
User entered 'None (0)'	System	11 Oct 2020 17:22:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:22:04', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'e325d46d-b737-49bb-a43f-22513f047230'	System	11 Oct 2020 17:22:38
User entered 'None (0)'	System	11 Oct 2020 17:22:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:22:07', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'e325d46d-b737-49bb-a43f-22513f047230'	System	11 Oct 2020 17:22:38
User entered 'None (0)'	System	11 Oct 2020 17:22:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:22:09', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'e325d46d-b737-49bb-a43f-22513f047230'	System	11 Oct 2020 17:22:38
User entered 'None (0)'	System	11 Oct 2020 17:22:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:22:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'e325d46d-b737-49bb-a43f-22513f047230'	System	11 Oct 2020 17:22:38
User entered 'None (0)'	System	11 Oct 2020 17:22:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:22:18', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'e325d46d-b737-49bb-a43f-22513f047230'	System	11 Oct 2020 17:22:38
User entered 'None (0)'	System	11 Oct 2020 17:22:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:22:25', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'e325d46d-b737-49bb-a43f-22513f047230'	System	11 Oct 2020 17:22:38
User entered 'No (N)'	System	11 Oct 2020 17:22:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-11T13:22:35', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'e325d46d-b737-49bb-a43f-22513f047230'	System	11 Oct 2020 17:22:38
User entered '11 Oct 2020 13:22'	System	11 Oct 2020 17:22:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 6'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:17', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7eb9c7c6-540d-4c82-9c9a-893365905f22'	System	12 Oct 2020 18:12:48
User entered 'None (0)'	System	12 Oct 2020 18:12:48

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:19', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7eb9c7c6-540d-4c82-9c9a-893365905f22'	System	12 Oct 2020 18:12:48
User entered 'None (0)'	System	12 Oct 2020 18:12:48

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:22', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7eb9c7c6-540d-4c82-9c9a-893365905f22'	System	12 Oct 2020 18:12:48
User entered 'None (0)'	System	12 Oct 2020 18:12:48

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:26', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7eb9c7c6-540d-4c82-9c9a-893365905f22'	System	12 Oct 2020 18:12:48
User entered 'None (0)'	System	12 Oct 2020 18:12:48

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:31', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7eb9c7c6-540d-4c82-9c9a-893365905f22'	System	12 Oct 2020 18:12:48
User entered 'None (0)'	System	12 Oct 2020 18:12:48

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:34', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7eb9c7c6-540d-4c82-9c9a-893365905f22'	System	12 Oct 2020 18:12:48
User entered 'None (0)'	System	12 Oct 2020 18:12:48

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:41', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7eb9c7c6-540d-4c82-9c9a-893365905f22'	System	12 Oct 2020 18:12:48
User entered 'No (N)'	System	12 Oct 2020 18:12:48

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-12T14:12:45', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '7eb9c7c6-540d-4c82-9c9a-893365905f22'	System	12 Oct 2020 18:12:48
User entered '12 Oct 2020 14:12'	System	12 Oct 2020 18:12:48

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
Data entry locked.	System	07 Oct 2020 12:42:26
User entered 'Day 7'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:09', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '992c27f0-5369-40ed-ad72-0c2a1e88e95e'	System	14 Oct 2020 13:30:38
User entered 'None (0)'	System	14 Oct 2020 13:30:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:12', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '992c27f0-5369-40ed-ad72-0c2a1e88e95e'	System	14 Oct 2020 13:30:38
User entered 'None (0)'	System	14 Oct 2020 13:30:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:14', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '992c27f0-5369-40ed-ad72-0c2a1e88e95e'	System	14 Oct 2020 13:30:38
User entered 'None (0)'	System	14 Oct 2020 13:30:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:17', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '992c27f0-5369-40ed-ad72-0c2a1e88e95e'	System	14 Oct 2020 13:30:38
User entered 'None (0)'	System	14 Oct 2020 13:30:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:20', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '992c27f0-5369-40ed-ad72-0c2a1e88e95e'	System	14 Oct 2020 13:30:38
User entered 'None (0)'	System	14 Oct 2020 13:30:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:22', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '992c27f0-5369-40ed-ad72-0c2a1e88e95e'	System	14 Oct 2020 13:30:38
User entered 'None (0)'	System	14 Oct 2020 13:30:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:30', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '992c27f0-5369-40ed-ad72-0c2a1e88e95e'	System	14 Oct 2020 13:30:38
User entered 'No (N)'	System	14 Oct 2020 13:30:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2020-10-14T09:30:33', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '992c27f0-5369-40ed-ad72-0c2a1e88e95e'	System	14 Oct 2020 13:30:38
User entered '14 Oct 2020 09:30'	System	14 Oct 2020 13:30:38

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:29:02
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 12:42:26

US3222554

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:29:10
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:29:02
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 12:42:26

US3222554

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:06:53

US3222554

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '14 Oct 2020'	Alicia Cevera (b) (4)	09 Nov 2020 19:06:53

US3222554

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:06:53

US3222554

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:06:53

US3222554

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:07:29

US3222554

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'I'	System	09 Nov 2020 19:07:29

US3222554

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:07:48

US3222554

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '21 Oct 2020'	Alicia Cevera (b) (4)	09 Nov 2020 19:07:48

US3222554

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:07:48

US3222554

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:07:48

US3222554

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	09 Nov 2020 19:08:13

US3222554

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'I'	System	09 Nov 2020 19:08:13

US3222554

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	09 Nov 2020 19:09:19

US3222554

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '28 Oct 2020'	Alicia Cevera (b) (4)	09 Nov 2020 19:09:19

US3222554

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:09:19

US3222554

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:09:19

US3222554

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:09:32

US3222554

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'I'	System	09 Nov 2020 19:09:32

US3222554

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:17

US3222554

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '9 Nov 2020'	Alicia Cevera (b) (4)	09 Nov 2020 19:10:17

US3222554

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'Clinic (Clinic)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:17

US3222554

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'VISIT3'	System	09 Nov 2020 19:10:17

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'No (N)'	Alicia Cevera (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered empty.	System	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered empty.	System	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered empty.	System	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered empty.	System	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	Alicia Cevera (b) (4)	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered empty.	System	09 Nov 2020 19:10:27

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21

US3222554

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21

US3222554

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:33

US3222554

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:33

US3222554

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:47

US3222554

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '9 Nov 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:10:47

US3222554

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered '09:00'	Alicia Cevera (b) (4)	09 Nov 2020 19:10:47

US3222554

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered '9 Nov 2020 09:00'	System	09 Nov 2020 19:10:47

US3222554

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:43:19
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	09 Nov 2020 19:11:00

US3222554

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:21
User entered 'I'	System	09 Nov 2020 19:11:00

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 64'	System	07 Sep 2020 15:10:36

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17
Data entry locked.	System	07 Sep 2020 15:10:36
User entered '07 Nov 2020 00:01'	System	07 Sep 2020 15:10:36

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17
Data entry locked.	System	07 Sep 2020 15:10:36
User entered '11 Nov 2020 23:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17
Data entry locked.	System	07 Sep 2020 15:10:36
User entered 'Day 71'	System	07 Sep 2020 15:10:36

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:06:57

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17
Data entry locked.	System	07 Sep 2020 15:10:36
User entered '14 Nov 2020 00:01'	System	07 Sep 2020 15:10:36

US3222554

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:39:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:52:17
Data entry locked.	System	07 Sep 2020 15:10:36
User entered '18 Nov 2020 23:59'	System	07 Sep 2020 15:10:36

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:52:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 05:52:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 05:52:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:52:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 05:52:17

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 05:52:17

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:52:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 05:52:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:52:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2021-01-13T22:03:45', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ebde4bdf-77ce-43bc-bb9c-9fc25633a1a2'	System	14 Jan 2021 03:04:10
User entered 'No (N)'	System	14 Jan 2021 03:04:10

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2021-01-13T22:03:56', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ebde4bdf-77ce-43bc-bb9c-9fc25633a1a2'	System	14 Jan 2021 03:04:10
User entered 'No (N)'	System	14 Jan 2021 03:04:10

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2021-01-13T22:04:05', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ebde4bdf-77ce-43bc-bb9c-9fc25633a1a2'	System	14 Jan 2021 03:04:10
User entered '13 Jan 2021 22:04:05'	System	14 Jan 2021 03:04:10

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2021-02-14T19:07:58', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '28427042-dc82-40ff-916d-65c70d0aa54e'	System	15 Feb 2021 00:11:07
User entered 'No (N)'	System	15 Feb 2021 00:11:07

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2021-02-14T19:08:02', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '28427042-dc82-40ff-916d-65c70d0aa54e'	System	15 Feb 2021 00:11:07
User entered 'No (N)'	System	15 Feb 2021 00:11:07

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2021-02-14T19:08:07', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: '28427042-dc82-40ff-916d-65c70d0aa54e'	System	15 Feb 2021 00:11:07
User entered '14 Feb 2021 19:08:07'	System	15 Feb 2021 00:11:07

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 05:52:17

US3222554

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:57

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:52:17
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 05:52:17

US3222554

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:06:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2021-04-19T17:24:31-04:00', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ee54c745-9530-4c5b-9485-2d378784f568'	System	19 Apr 2021 21:24:47
User entered 'No (N)'	System	19 Apr 2021 21:24:47

US3222554

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:06:57

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:32:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (98be616573cdd81b)', Time: '2021-04-19T17:24:40-04:00', User OID: 'PatientReportedOutcome (US3222554)', ODM File OID: 'ee54c745-9530-4c5b-9485-2d378784f568'	System	19 Apr 2021 21:24:47
User entered '19 Apr 2021 17:24:40'	System	19 Apr 2021 21:24:47

US3222554

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:22:55

US3222554

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:22:55

US3222554

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:22:55

US3222554

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:22:55

US3222554

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:16:59

US3222554

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 00:10:10
User entered 'I'	System	16 Dec 2020 16:16:59

US3222554

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	06 Jan 2021 15:22:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 21:52:46
Query 'Data is required. Please complete.' answered with 'transcript error ' (Site from System).		16 Dec 2020 17:50:28
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 17:50:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 17:50:06
User entered 'Yes (Y)'		16 Dec 2020 17:48:05

US3222554

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:22:11
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Dec 2020 17:50:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 17:50:12
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	16 Dec 2020 17:50:06
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	16 Dec 2020 17:50:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Dec 2020 17:50:06
User entered ' 2020' (non-conformant).	(b) (4), (b) (6)	16 Dec 2020 17:50:06
User entered '30 Nov 2020' reason for change: Data Entry Error		16 Dec 2020 17:49:27
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	16 Dec 2020 17:48:05
User entered '02 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 17:48:05

US3222554

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:22:11
User entered empty; reason for change Data Entry Error		16 Dec 2020 17:50:06
User entered 'Contact Made (CONTACT MADE)'		16 Dec 2020 17:48:05

US3222554

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 17:48:05

US3222554

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:25:30

US3222554

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User entered 'I'	System	06 Jan 2021 15:25:30

US3222554

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:32:06

US3222554

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:32:06

US3222554

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:32:06

US3222554

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:32:06

US3222554

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 13:31:45

US3222554

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User entered 'I'	System	17 Feb 2021 13:31:45

US3222554

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:11:21

US3222554

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:11:21

US3222554

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:11:21

US3222554

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:11:21

US3222554

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:11:29

US3222554

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:38:51
User entered 'I'	System	04 Mar 2021 15:11:29

US3222554

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:13

US3222554

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:13

US3222554

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:13

US3222554

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	15 Apr 2021 19:49:13

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:49:20

US3222554

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:25

US3222554

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 19:49:25

US3222554

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:43

US3222554

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:43

US3222554

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '11:00'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:43

US3222554

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 11:00'	System	15 Apr 2021 19:49:43

US3222554

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:49:47

US3222554

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 19:49:47

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:54:50

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:54:50

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:54:50

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'UNBLND_DECIDE'	System	15 Feb 2021 10:54:50

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '31 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:44:10
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:30:42

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Diana Toney (b) (4)	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:44:10
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:30:42

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '31 Jan 2021'	Diana Toney (b) (4)	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Placebo (Placebo)'	Diana Toney (b) (4)	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered '1'	System	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:57

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'I'	System	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered empty.	System	15 Feb 2021 11:33:55
DataPoint set to visible.	System	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered empty.	System	15 Feb 2021 11:33:55
DataPoint set to visible.	System	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User accepted default value 'Pre-Dose (PREDOSE)'		15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	15 Feb 2021 11:34:17
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	15 Feb 2021 11:33:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:34:17
User entered '14 Feb 2021'		15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered empty.	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered empty.	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered empty.	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered empty.	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered empty.	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:57

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered empty.	System	15 Feb 2021 11:33:55
DataPoint set to visible.	System	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User accepted default value 'Post-Dose (POSTDOSE)'		15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '12:26'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered '14 Feb 2021 12:26'	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '69'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'bpm'	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'breaths/min'	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '128'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'mmHg'	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '78'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'mmHg'	System	15 Feb 2021 11:33:55

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:34:27

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:34:27

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:34:40

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:34:40

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:34:40

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'mRNA-1273'	System	15 Feb 2021 11:34:40
DataPoint set to visible.	System	31 Jan 2021 20:46:36

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:34:40

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '11:56'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:34:40

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered '14 Feb 2021 11:56'	System	15 Feb 2021 11:34:40

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:34:40

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'ONCE'	System	15 Feb 2021 11:34:40

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 11:34:40

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:35:15

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:35:15

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '11:30'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:35:15

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered '14 Feb 2021 11:30'	System	15 Feb 2021 11:35:15

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:35:25

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:57

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:35:25

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:57

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '11:33'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:35:25

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:57

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered '14 Feb 2021 11:33'	System	15 Feb 2021 11:35:25

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:35:31

US3222554

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:26
User entered 'I'	System	15 Feb 2021 11:35:31

US3222554

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 16:53:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:02:44

US3222554

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 16:53:26
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:02:44

US3222554

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 16:53:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:02:44

US3222554

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 16:53:26
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:02:44

US3222554

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	23 Feb 2021 16:53:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 22:02:50

US3222554

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'I'	System	22 Feb 2021 22:02:50

US3222554

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered '1'	System	22 Feb 2021 22:02:50
DataPoint set to visible.	System	22 Feb 2021 22:02:50

US3222554

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:00:02

US3222554

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '15 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:00:02

US3222554

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Clinic (Clinic)'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:00:02

US3222554

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'OLD29'	System	30 Mar 2021 12:00:02

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User accepted default value 'Pre-Dose (PREDOSE)'	douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '15 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '10:26'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered '15 Mar 2021 10:26'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '37.0' C	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Oral (Oral)'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '69'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'bpm'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '18'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'breaths/min'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '126'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'mmHg'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '68'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'mmHg'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User accepted default value 'Post-Dose (POSTDOSE)'	douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '15 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '11:08'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered '15 Mar 2021 11:08'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '37.0' C	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Oral (Oral)'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '74'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'bpm'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '18'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'breaths/min'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '127'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'mmHg'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '96'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'mmHg'	System	30 Mar 2021 12:01:28

US3222554

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:37

US3222554

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '15 Mar 2021'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:01:37

US3222554

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:02:00

US3222554

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:02:00

US3222554

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:02:00

US3222554

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'mRNA-1273'	System	30 Mar 2021 12:02:00
DataPoint set to visible.	System	22 Feb 2021 22:02:50

US3222554

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '15 Mar 2021'	douglas winter (b) (4)	30 Mar 2021 12:02:00

US3222554

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '10:38'	(b) (4) douglas winter (b) (4) (b) (4)	30 Mar 2021 12:02:00

US3222554

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered '15 Mar 2021 10:38'	System	30 Mar 2021 12:02:00

US3222554

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) douglas winter (b) (4)	30 Mar 2021 12:02:00
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'ONCE'	System	30 Mar 2021 12:02:00

US3222554

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:57

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'INTRAMUSCULAR'	System	30 Mar 2021 12:02:00

US3222554

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:11:19

US3222554

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'I'	System	22 Mar 2021 17:11:19

US3222554

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:44:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:11:40

US3222554

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:44:10
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:11:40

US3222554

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:44:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:11:40

US3222554

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:57

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:44:10
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:11:40

US3222554

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:44:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:11:47

US3222554

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:57

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:08:33
User entered 'I'	System	22 Mar 2021 17:11:47

US3222554

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:47:57

US3222554

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:47:57

US3222554

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:47:57

US3222554

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:57

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	15 Apr 2021 19:47:57

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:57

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:48:02

US3222554

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:08

US3222554

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:57

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:08

US3222554

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:17

US3222554

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:17

US3222554

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '11:00'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:48:17

US3222554

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:57

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 11:00'	System	15 Apr 2021 19:48:17

US3222554

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:06:57

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:40
DataPoint Verified.		30 Mar 2021 17:05:57
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Alicia Cevera (b) (4)	01 Feb 2021 13:24:12
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	09 Oct 2020 15:45:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 17:20:10
User entered		
'USA-US104-2021-mRNA-1273-P301000006'	System	02 Feb 2021 17:20:04
User entered 'New'	(b) (4), (b) (6)	02 Feb 2021 17:20:04

US3222554

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 14:59:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 14:59:28
Data point term sent to Coder	System	01 Feb 2021 14:58:57
User entered 'Diverticulitis'	Diana Toney (b) (4)	01 Feb 2021 14:58:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:12:34
User entered '24 Jan 2021' reason for change: Data Entry Error		19 Apr 2021 12:12:34
DataPoint Verified.		19 Mar 2021 18:11:09
User entered '28 Jan 2021' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:57:04
User entered '24 Jan 2021'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	03 Mar 2021 13:57:04
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	01 Feb 2021 14:58:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
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).		04 Mar 2021 16:16:33
User entered '07 Feb 2021' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 14:01:53
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	03 Mar 2021 13:57:04
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	03 Mar 2021 13:57:04
User entered '30 Jan 2021' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:57:04
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	03 Mar 2021 13:36:56
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 'ONGOING WITH NEW BASELINE' (Site from Safety).	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:04:44
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)	08 Feb 2021 19:52:16
User entered empty.	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:57:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

US3222554

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	Diana Toney (b) (4)	01 Feb 2021 14:58:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	Diana Toney (b) (4)	01 Feb 2021 14:58:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant)' canceled (Site from Safety).		02 Mar 2021 13:19:04
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).		22 Feb 2021 16:35:39
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		08 Feb 2021 19:54:51
Query 'V Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).		08 Feb 2021 19:53:37
User opened query 'V Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		08 Feb 2021 19:52:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant)' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:51:55
User entered '1'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	21 Apr 2021 19:52:26
User closed query 'Discharge summary indicates that subject was admitted 28Jan2021, please confirm and revise if needed.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:52:24
Query 'Discharge summary indicates that subject was admitted 28Jan2021, please confirm and revise if needed.' answered with 'revised to 28 Jan 2021' (Site from CRA).		19 Apr 2021 11:45:18
User entered '28 Jan 2021' reason for change: Data Entry Error		19 Apr 2021 11:44:57
User opened query 'Discharge summary indicates tha subject was admitted 28Jan2021, please confirm and revise if needed.' (Site from CRA).		19 Mar 2021 18:13:31
DataPoint Un-verified.		19 Mar 2021 18:11:18
DataPoint Verified.		19 Mar 2021 18:11:09
User entered '29 Jan 2021'	Diana Toney (b) (4)	01 Feb 2021 14:58:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '30 Jan 2021'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	Diana Toney (b) (4)	01 Feb 2021 14:58:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	Diana Toney (b) (4)	01 Feb 2021 14:58:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Related (NOT RELATED)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User closed query 'PV Query: As the last dose of placebo was given on 07 Oct 2020, please update the action taken with placebo from dose delayed to not applicable.' (Site from Safety).		04 Mar 2021 16:16:16
Query 'PV Query: As the last dose of placebo was given on 07 Oct 2020, please update the action taken with placebo from dose delayed to not applicable.' answered with 'CORRECTED TO NOT APPLICABLE' (Site from Safety).	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:30:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:30:00
User opened query 'PV Query: As the last dose of placebo was given on 07 Oct 2020, please update the action taken with placebo from dose delayed to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:53:27
User entered 'Dose Delayed (DOSE DELAYED)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	Diana Toney (b) (4)	01 Feb 2021 14:58:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		04 Mar 2021 09:17:44
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'CORRECTED THE CONMED PAGE/ANTIBIOTICS TO SHOW THEIR INDICATION WAS TO TREAT DIVERTICULITIS.' (Site from DM).	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:36:12
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 12:23:00
User entered 'I'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 13:24:27
User closed query 'Source indicates subject had a concomitant procedure. Please confirm and revise if necessary.' (Site from CRA).		26 Apr 2021 13:24:25
Query 'Source indicates subject had a concomitant procedure. Please confirm and revise if necessary.' answered with 'updated under concomitant procedure as ABD/PELVIS W/CONT-CT SCAN' (Site from CRA).		19 Apr 2021 12:09:08
User entered '1' reason for change: Data Entry Error		19 Apr 2021 12:03:48
User opened query 'Source indicates subject had a concomitant procedure. Please confirm and revise if necessary.' (Site from CRA).		19 Mar 2021 18:14:50
DataPoint Un-verified.		19 Mar 2021 18:13:45
DataPoint Verified.		19 Mar 2021 18:11:09
User entered '0'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		04 Mar 2021 16:16:21
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'RESOLVED' (Site from Safety).	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:57:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:36:56
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:52:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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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 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User closed query 'PV Query: The subject began to have symptoms from 24 Jan 2021, however the event start date has been updated to 28 Jan 2021. Kindly revise the event onsite date accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:02:08
Query 'PV Query: The subject began to have symptoms from 24 Jan 2021, however the event start date has been updated to 28 Jan 2021. Kindly revise the event onsite date accordingly.' answered with 'updated as 24 Jan 2021 for event start date. Revised on AE source as well.' (Site from Safety).		19 Apr 2021 12:13:39
DataPoint Verified.		19 Mar 2021 18:11:09
User opened query 'PV Query: The subject began to have symptoms from 24 Jan 2021, however the event start date has been updated to 28 Jan 2021. Kindly revise the event onsite date accordingly.' (Site from Safety).		10 Mar 2021 18:35:59
User closed query 'Per DM CLR: Narrative = SAW HIS PCP AND WAS GIVEN ORAL ANTIBIOTICS . However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		04 Mar 2021 09:20:23
User closed query 'Per DM CLR: Narrative = IV ANTIBIOTICS . However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		04 Mar 2021 09:18:09

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HERE FOR PARTICIPATION DECISION CLINIC VISIT, PT STATED HE WAS ADMITTED TO THE HOSPITAL FOR DIVERTICULITIS ON JAN 29 2021 AND WAS DISCHARGED ON JAN 30 2021. PATIENT STATED HIS SYMPTOMS OF ABDOMINAL PAIN STARTED ON JAN 24TH 2021 AND SAW HIS PCP AND WAS GIVEN ORAL ANTIBIOTICS BUT THE PAIN PERSISTED AND PATIENT SOUGHT MEDICAL ATTENTION AT THE HOSPITAL ON JAN 29 2021 FOR IV ANTIBIOTICS HE WAS DISCHARGED ON JAN 30TH 2021 WITH ORAL ANTIBIOTICS FLAGYL 500MG FOR 7 DAYS AND CIPRO 500MG TWICE A DAY FOR 7 DAYS. (UPDATED RECOVERED/RESOLVED DATE TO 07/FEB/2021 WHICH IS THE STOP DATE FOR HIS ORAL ANTIBIOTICS). A REQUEST FOR MEDICAL RECORDS WAS SENT ON JANUARY 31, 2021.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 14:01:53
Query 'Per DM CLR: Narrative = SAW HIS PCP AND WAS GIVEN ORAL ANTIBIOTICS . However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED ORAL FLAGYL AND CIPRO PLUS INDICATION ON CONMED PAGE.' (Site from DM).	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:59:51
Query 'Per DM CLR: Narrative = IV ANTIBIOTICS . However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED ANTIBIOTICS ON CONMED PAGE' (Site from DM).	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:58:25
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.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4)	02 Mar 2021 13:19:43

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = SAW HIS PCP AND WAS GIVEN ORAL ANTIBIOTICS . However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 12:22:54
User opened query 'Per DM CLR: Narrative = IV ANTIBIOTICS . However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		21 Feb 2021 12:22:48
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).		08 Feb 2021 19:53:15
User entered 'Patient here for participation decision clinic visit, pt stated he was admitted to the hospital for diverticulitis on Jan 29 2021 and was discharged on Jan 30 2021. Patient stated his symptoms of abdominal pain started on Jan 24th 2021 and saw his PCP and was given oral antibiotics but the pain persisited and patient sought medical attention at the hospital on Jan 29 2021 for IV antibiotics he was discharged on Jan 30th 2021 with oral antibiotics flagyl 500mg for 7 days and cipro 500mg twice a day for 7 days. A request for medical records was sent on January 31, 2021.'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 14:58:04

US3222554

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 14:58:04

US3222554

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Feb 2021 14:58:04

US3222554

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Feb 2021 14:58:04

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Rib pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Mar 2021 20:53:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Mar 2021 20:53:58
Data point term sent to Coder	System	03 Mar 2021 13:18:03
User entered 'RIB PAIN RIGHT SIDE'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '14 Feb 2021'	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User closed query 'Data is required. Please provide.' (Site from System).		11 Mar 2021 09:54:35
Query 'Data is required. Please provide.' answered with 'time is unknown ' (Site from System).	Crystal Paccione (b) (4) (b) (4)	09 Mar 2021 20:17:19
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Mar 2021 13:17:40
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'I'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

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 15:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4)	03 Mar 2021 13:17:40
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:06:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 13:17:40

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Aural disorders NEC, HLT: Ear disorders NEC, PT: Ear pain, LLT: Otalgia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 13:20:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 13:20:57
	(b) (4)	
Data point term sent to Coder	System	03 Mar 2021 13:20:04
User entered 'OTALGIA'	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 13:19:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 13:19:23
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	03 Mar 2021 13:19:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 13:19:10
User entered empty.	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '14 Feb 2021'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Mar 2021 13:29:26
User entered '00:00' reason for change: Data Entry Error	douglas winter (b) (4)	03 Mar 2021 13:29:26
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Mar 2021 13:19:10
User entered empty.	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Feb 2021 00:00'	System	03 Mar 2021 13:29:26
User entered empty.	System	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'I'	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

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 15:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4)	03 Mar 2021 13:19:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:06:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 13:19:10

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 00:05:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 00:05:49
Data point term sent to Coder	System	03 Mar 2021 13:24:07
User entered 'MYALGIA RIGHT SIDE OF BODY'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '14 Feb 2021'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Apr 2021 07:54:20
Query 'Data is required. Please provide.' answered with 'updated. removed times' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 12:20:16
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 12:20:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 12:20:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 12:20:04
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '13:00'	douglas winter (b) (4)	03 Mar 2021 13:23:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User entered empty.	System	19 Apr 2021 12:20:04
User entered '14 Feb 2021 13:00'	System	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Mar 2021 13:23:55
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:55
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Mar 2021 13:23:44
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '24 Feb 2021'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User closed query 'Per CDM: As per CCG, this field is not required, unless Start and End time is within 24 hours of dosing, please update it accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:24:10
User closed query 'Data is required. Please provide.' (Site from System).		20 Apr 2021 07:54:28
Query 'Data is required. Please provide.' answered with 'updated. removed times' (Site from System).		19 Apr 2021 12:19:59
Query 'Per CDM: As per CCG, this field is not required, unless Start and End time is within 24 hours of dosing, please update it accordingly' answered with 'updated. removed times since both start and end times were not within 24 hours of dosing' (Site from DM).		19 Apr 2021 12:19:44
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 12:17:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 12:17:57
User entered empty; reason for change Data Entry Error		19 Apr 2021 12:17:57
DataPoint Verified.		19 Mar 2021 18:11:09
User opened query 'Per CDM: As per CCG, this field is not required, unless Start and End time is within 24 hours of dosing, please update it accordingly' (Site from DM).		11 Mar 2021 15:44:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Mar 2021 13:24:25
User entered '00:00' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:24:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Mar 2021 13:24:10
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Mar 2021 13:24:10
User entered 'UN:UN' (non-conformant).	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:24:10
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Mar 2021 13:23:55

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User entered empty.	System	19 Apr 2021 12:17:57
User entered '24 Feb 2021 00:00'	System	03 Mar 2021 13:24:25
User entered '24 Feb 2021 UN:UN' (non-conformant).	System	03 Mar 2021 13:24:10
User entered empty.	System	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'l'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered '0'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:11:09
User entered empty.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User entered '0'	System	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32
User entered '0'	System	03 Mar 2021 13:23:44

US3222554

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:06:57

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:40
User closed query 'ConMeds captured in SAE hospital records pending entry in EDC and on source log. Please respond to query once ConMeds are added in both locations. ' (Site from CRA).		28 Apr 2021 20:17:08
Query 'ConMeds captured in SAE hospital records pending entry in EDC and on source log. Please respond to query once ConMeds are added in both locations. ' answered with 'meds from hos updated in con med list and edc' (Site from CRA).	Diana Toney (b) (4) (b) (4)	23 Apr 2021 18:39:58
User opened query 'ConMeds captured in SAE hospital records pending entry in EDC and on source log. Please respond to query once ConMeds are added in both locations. ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:16:39
DataPoint Verified.		30 Mar 2021 17:07:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 20:41:53
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 11:44:30

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 09:46:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:29:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:29:04
Data point term sent to Coder	System	03 Mar 2021 13:28:12
Query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate. ' answered with 'CORRECTED SPELLING ERROR' (Site from DM).	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:28:09
Coding entries removed.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:27:57
User entered 'AMBIEN' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:27:57
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:14:27

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, PRODUCT: AMMONIUM SUCCINATE;CALCIUM SUCCINATE;GLUTAMATE SODIUM;GLYCINE;MAGNESIUM SUCCINATE;TOCOPHERYL ACETATE;ZINC DIFUMARATE HYDRATE, PRODUCTSYNONYM: AMBEREN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 11:17:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 11:17:40
Data point term sent to Coder	System	11 Sep 2020 11:45:55
User entered 'AMBREN'	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 11:45:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:05:38
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 19:29:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 18:24:51
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).		02 Nov 2020 09:01:15
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 11:45:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'INSOMNIA'	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'UNK'	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'as needed (PRN)'	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'UN UNK 2005'	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	11 Sep 2020 11:45:25
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:45:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:45:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:45:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Nov 2020 19:31:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 19:31:51
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	14 Nov 2020 19:30:44 14 Nov 2020 19:30:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:47:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:47:33
Data point term sent to Coder User entered 'COLACE'	System Amber Vasquez (b) (4)	11 Sep 2020 11:46:55 11 Sep 2020 11:46:37

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 09:47:25
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'CHANGED TO NO' (Site from DM).	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:28:42
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:28:31
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:16:10
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 11:46:37

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User closed query 'Per DM CLR: Please update INDICATION to reflect the actual medical condition the med is being used to prevent/treat rather than the type of medication/mechanism of action. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:06:58
Query 'Per DM CLR: Please update INDICATION to reflect the actual medical condition the med is being used to prevent/treat rather than the type of medication/mechanism of action. Please review and update accordingly. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 19:31:50
User entered 'CONSTIPATION' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 19:30:36
User opened query 'Per DM CLR: Please update INDICATION to reflect the actual medical condition the med is being used to prevent/treat rather than the type of medication/mechanism of action. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:01:32
User entered 'STOOL SOFTNER'	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 11:46:37

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'UNK'	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Other (OTHER)'	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	11 Sep 2020 11:47:01
User entered 'UNKNOWN' reason for change: Data Entry Error	Amber Vasquez (b) (4)	11 Sep 2020 11:47:01
	(b) (4)	
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	11 Sep 2020 11:46:37
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'as needed (PRN)'	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'UN UNK 2010'	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	11 Sep 2020 11:46:37
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:46:37

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:46:37

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:46:37

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
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) Coder Import (b) (4) (b) (4)	11 Sep 2020 11:48:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:48:33
Data point term sent to Coder	System	11 Sep 2020 11:47:56
User entered 'LISINOPRIL'	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 11:47:43

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:07:26
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 19:32:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 18:25:17
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition tha match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).		02 Nov 2020 09:01:50
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 11:47:43

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'HYPERTENSION'	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered '10'	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'UN UNK 2005'	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	11 Sep 2020 11:47:43
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:47:43

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:47:43

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:47:43

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 11:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:49:34
Data point term sent to Coder	System	11 Sep 2020 11:48:56
User entered 'PRAVASTATIN'	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 11:48:20

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User closed query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:07:39
Query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 19:32:13
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 19:32:08
User opened query 'Per DM CLR: Prophylaxis = YES. However, there is a recorded MH condition that match the indication. Please review and update Prophylaxis to NO as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:02:05
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 11:48:20

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'HYPERLIPIDEMIA'	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered '5'	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'UN UNK 2005'	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	11 Sep 2020 11:48:20
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:48:20

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:48:20

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:48:20

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:06:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:06:30
Data point term sent to Coder	System	04 Nov 2020 18:23:49
User entered 'INFLUENA VACCINE'	(b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'SEASONAL INFLUENZA'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Signature has been broken.	Diana Toney (b) (4)	23 Apr 2021 18:15:56
User entered '0.5' reason for change: Data Entry Error	Diana Toney (b) (4)	23 Apr 2021 18:15:56
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User closed query 'Per CDM: Response noted. Please review Dose unit to be blank as Dose per administration is recorded as "UNK". Please update accordingly. Else clarify' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 13:25:20
Query 'Per CDM: Response noted. Please review Dose unit to be blank as Dose per administration is recorded as "UNK". Please update accordingly. Else clarify' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	14 Dec 2020 15:16:54
User opened query 'Per CDM: Response noted. Please review Dose unit to be blank as Dose per administration is recorded as "UNK". Please update accordingly. Else clarify' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 10:22:12
User closed query 'Per CDM: Please provide the actual dose for 'SEASONAL INFLUENZA' rather than the number of injections. Update the 'Dose' and 'Dose Unit' fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 10:21:43
Query 'Per CDM: Please provide the actual dose for 'SEASONAL INFLUENZA' rather than the number of injections. Update the 'Dose' and 'Dose Unit' fields as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	04 Dec 2020 16:07:53
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4)	04 Dec 2020 16:07:49
User opened query 'Per CDM: Please provide the actual dose for 'SEASONAL INFLUENZA' rather than the number of injections. Update the 'Dose' and 'Dose Unit' fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 22:04:09
User entered '1'	(b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Signature has been broken.	Diana Toney (b) (4)	23 Apr 2021 18:15:56
User entered 'mg (mg)' reason for change: Data Entry Error	Diana Toney (b) (4)	23 Apr 2021 18:15:56
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Other (OTHER)'	(b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Signature has been broken.	Diana Toney (b) (4)	23 Apr 2021 18:15:56
User entered empty; reason for change Data Entry Error	Diana Toney (b) (4)	23 Apr 2021 18:15:56
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'UNKNOWN' reason for change: Data Entry Error	Albert Garcia (b) (4)	14 Dec 2020 15:16:49
User closed query 'Per CDM: Response for Dose unit is recorded as "Injection", however it signifies 'Route of administration'.Please review and update the data as appropriate,else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 22:04:02
Query 'Per CDM: Response for Dose unit is recorded as "Injection", however it signifies 'Route of administration'.Please review and update the data as appropriate,else clarify.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	14 Nov 2020 19:32:28
User entered 'DOSE' reason for change: Data Entry Error	Albert Garcia (b) (4)	14 Nov 2020 19:32:24
User opened query 'Per CDM: Response for Dose unit is recorded as "Injection", however it signifies 'Route of administration'.Please review and update the data as appropriate,else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 17:12:41
User entered 'INJECTION'		04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User entered empty.	System	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User entered empty.	System	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:58:41
User entered empty.	System	04 Nov 2020 18:23:25

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:16:09
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 13:35:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:35:57
Data point term sent to Coder	System	03 Mar 2021 13:35:22
Coding entries removed.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:34:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:26:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:26:28
Data point term sent to Coder	System	01 Feb 2021 15:05:59
User entered 'flagyl'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:16:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:16:12
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'DIVERTICULITIS' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	03 Mar 2021 13:34:28
	(b) (4)	
User entered 'antibiotic'	Diana Toney (b) (4)	01 Feb 2021 15:05:15
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:16:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '500'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:16:19
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'mg (mg)'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:16:25
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
User closed query 'Please confirm frequency. Frequency not captured in source. ' (Site from CRA). User signature succeeded.	(b) (4)	28 Apr 2021 20:17:51
	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
Query 'Please confirm frequency. Frequency not captured in source. ' answered with 'confirmed dose on source' (Site from CRA). Signature has been broken.	Diana Toney (b) (4)	23 Apr 2021 18:20:08
	(b) (4)	
	Diana Toney (b) (4)	23 Apr 2021 18:20:02
	(b) (4)	
User entered 'three times daily (TID)' reason for change: Data Entry Error	Diana Toney (b) (4)	23 Apr 2021 18:20:02
	(b) (4)	
User opened query 'Please confirm frequency. Frequency not captured in source. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:22:11
		30 Mar 2021 18:20:55
DataPoint Verified.		30 Mar 2021 18:17:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'once daily (QD)'	Diana Toney (b) (4)	01 Feb 2021 15:05:15
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Un-verified.		30 Mar 2021 18:20:57
DataPoint Verified.		30 Mar 2021 18:17:18
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:17:19
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Oral (ORAL)'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:17:22
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:17:25
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '31 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:17:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '0'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:17:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	03 Mar 2021 13:26:38
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	01 Feb 2021 15:05:15
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:17:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '07 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	03 Mar 2021 13:26:38
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	01 Feb 2021 15:05:15
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
DataPoint Verified.		30 Mar 2021 18:17:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
User entered '3'	System	23 Apr 2021 18:20:02
User entered '1'	System	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
User entered '1'	System	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:30
User entered '804 (804)'	System	01 Feb 2021 15:05:15

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:19:19
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN, PRODUCTSYNONYM: CIPRO [CIPROFLOXACIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 13:35:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:35:58
Data point term sent to Coder	System	03 Mar 2021 13:35:23
Coding entries removed.	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:34:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN, PRODUCTSYNONYM: CIPRO [CIPROFLOXACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 08:06:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 08:06:44
Data point term sent to Coder	System	01 Feb 2021 15:09:01
User entered 'Cipro'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:19:21
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:19:25
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'DIVERTICULITIS' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	03 Mar 2021 13:34:51
	(b) (4)	
User entered 'antibiotic'	Diana Toney (b) (4)	01 Feb 2021 15:08:53
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:19:26
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '500'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:19:31
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'mg (mg)'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:20:22
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
User closed query 'Please confirm frequency. Frequency not captured in source. ' (Site from CRA).		28 Apr 2021 20:18:01
Query 'Please confirm frequency. Frequency not captured in source. ' answered with 'confirmed dose' (Site from CRA).	Diana Toney (b) (4) (b) (4)	23 Apr 2021 18:19:01
User opened query 'Please confirm frequency. Frequency not captured in source. ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 18:22:33
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:27:45
User entered 'twice daily (BID)'	Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:20:25
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Oral (ORAL)'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:20:27
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:20:30
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '31 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:20:32
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '0'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:20:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	03 Mar 2021 13:27:05
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	01 Feb 2021 15:08:53
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:20:36
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '07 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	03 Mar 2021 13:27:05
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	01 Feb 2021 15:08:53
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
DataPoint Verified.		30 Mar 2021 18:20:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) Diana Toney (b) (4) (b) (4)	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
User entered '2'	System	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
User entered '1'	System	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:08
User entered '804 (804)'	System	01 Feb 2021 15:08:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:51:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 13:57:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:57:05
Data point term sent to Coder	System	03 Mar 2021 13:56:36
User entered 'ZOSYN'	douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:51:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:51:37
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'DIVERTICULITIS'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:51:39
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '3.375'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:51:46
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'g (g)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:51:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4)	
	douglas winter (b) (4)	03 Mar 2021 13:55:42
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:51:55
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:51:57
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '100ML/HR, IVPB ONCE'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:51:59
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:52:01
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:52:03
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '29 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:52:08
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:52:10
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:52:12
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '29 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
DataPoint Verified.		30 Mar 2021 18:52:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
User entered empty.	System	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
User entered empty.	System	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:14
User entered empty.	System	03 Mar 2021 13:55:42

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
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) (b) (4)	31 Mar 2021 12:54:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 12:54:34
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:53:12
Data point term sent to Coder	System	30 Mar 2021 12:05:36
Coding entries removed.	douglas winter (b) (4) (b) (4)	30 Mar 2021 12:05:25
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) (b) (4)	16 Mar 2021 12:32:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 12:32:51
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:27:45
Data point term sent to Coder	System	03 Mar 2021 14:06:46
User entered 'MORPHINE'	douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:53:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User closed query 'Per DM CLR: Please note, there is a medical condition if DIVERTICULITIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 10:25:02
Query 'Per DM CLR: Please note, there is a medical condition if DIVERTICULITIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' answered with 'UPDATED INDICATION' (Site from DM).	douglas winter (b) (4) (b) (4)	30 Mar 2021 18:53:15
Signature has been broken.	douglas winter (b) (4) (b) (4)	30 Mar 2021 12:05:36
User entered 'DIVERTICULITIS' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Mar 2021 12:05:25
User opened query 'Per DM CLR: Please note, there is a medical condition if DIVERTICULITIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:17:31
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:27:45
User entered 'ABDOMINAL PAIN'	douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:00
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '2'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:04
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:07
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4)	
	douglas winter (b) (4)	03 Mar 2021 14:06:05
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:09
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:11
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:13
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '29 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:14
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:16
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:18
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '29 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
DataPoint Verified.		30 Mar 2021 18:56:19
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
User entered empty.	System	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
User entered empty.	System	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:36
User entered empty.	System	03 Mar 2021 14:06:05

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 18:57:30
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM HYDROXIDE, PRODUCTSYNONYM: MILK OF MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 14:08:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:08:59
Data point term sent to Coder	System	03 Mar 2021 14:07:47
User entered 'MILK OF MAGNESIUM'	douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 18:57:31
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:05:17
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'CONSTIPATION'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:05:19
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '30'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:05:21
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'mL (mL)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:07:42
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:07:45
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:07:51
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'BID/PRN'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:07:52
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:07:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:08:01
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '29 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:07:59
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:08:02
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:08:04
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '30 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
DataPoint Verified.		30 Mar 2021 19:08:06
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
User entered empty.	System	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
User entered empty.	System	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:00:54
User entered empty.	System	03 Mar 2021 14:07:45

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: ROXICODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:09:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:09:04
Data point term sent to Coder	System	30 Mar 2021 12:06:37
Coding entries removed.	douglas winter (b) (4) (b) (4)	30 Mar 2021 12:05:50
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:27:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: ROXICODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:53:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:53:06
Data point term sent to Coder	System	03 Mar 2021 14:52:51
User entered 'ROXICODONE'	douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:29
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
User closed query 'Per source "Abdominal Pain" please review source and confirm indication?' (Site from CRA).		28 Apr 2021 20:18:09
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Query 'Per source "Abdominal Pain" please review source and confirm indication?' answered with 'there is no source indicating abdominal pain during this time. AE/indication during this time period is diverticulitis. medical records confirm diverticulitis during this time as well' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:03:49
User closed query 'Per DM CLR: Please note, there is a medical condition if DIVERTICULITIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' (Site from DM).		31 Mar 2021 10:25:24
User opened query 'Per source "Abdominal Pain" please review source and confirm indication?' (Site from CRA).		30 Mar 2021 19:11:20
Query 'Per DM CLR: Please note, there is a medical condition if DIVERTICULITIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' answered with 'UPDATED INDICATION' (Site from DM).	douglas winter (b) (4) (b) (4)	30 Mar 2021 12:06:05
Signature has been broken.	douglas winter (b) (4) (b) (4)	30 Mar 2021 12:05:50
User entered 'DIVERTICULITIS' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Mar 2021 12:05:50
User opened query 'Per DM CLR: Please note, there is a medical condition if DIVERTICULITIS. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 12:16:53

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'ABDOMINAL PAIN'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:34
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '5'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:36
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:38
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:39
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Q4HR/PRN'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:42
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:43
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:47
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '29 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:48
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:50
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:51
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '30 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
DataPoint Verified.		30 Mar 2021 19:08:53
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
User entered empty.	System	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
User entered empty.	System	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:59:52
User entered empty.	System	03 Mar 2021 14:51:56

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
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)	23 Apr 2021 18:43:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:43:07
Data point term sent to Coder	System	23 Apr 2021 18:41:33
User entered 'aspirin'	Diana Toney (b) (4)	23 Apr 2021 18:41:04

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'cardiac'	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered '325'	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'mg (mg)'	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'once daily (QD)'	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'Oral (ORAL)'	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered '03 Jan 2010'	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered '0'	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:41:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 18:41:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Diana Toney (b) (4)	23 Apr 2021 18:41:09
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:41:04
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'No (N)'	Diana Toney (b) (4)	23 Apr 2021 18:41:04
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:41:04

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:41:04

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 18:41:04

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:43:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:43:53
Data point term sent to Coder User entered 'flexeril'	System Diana Toney (b) (4)	23 Apr 2021 18:42:34 23 Apr 2021 18:42:06

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'No (N)'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'back pain'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered '10'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'mg (mg)'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'three times daily (TID)'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'Oral (ORAL)'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'un UNK 2004'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered '0'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'No (N)'	Diana Toney (b) (4)	23 Apr 2021 18:42:06
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Apr 2021 18:42:06

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:42:06

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 18:42:06

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 18:45:10
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 18:45:10
Data point term sent to Coder	System	23 Apr 2021 18:43:35
User entered 'meloxicam'	Diana Toney (b) (4) (b) (4)	23 Apr 2021 18:43:03

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'No (N)'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'back pain'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered '15'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'mg (mg)'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'once daily (QD)'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'Oral (ORAL)'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'un UNK 2004'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered '0'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered empty.	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
	(b) (4)	
User entered 'No (N)'	Diana Toney (b) (4)	23 Apr 2021 18:43:03
	(b) (4)	

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:43:03

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:43:03

US3222554

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:57

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 18:43:03

US3222554

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:06:57

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:40
DataPoint Verified.		26 Apr 2021 13:24:41
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
Signature has been broken.	(b) (4)	
	douglas winter (b) (4)	03 Mar 2021 17:22:43
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	03 Mar 2021 17:22:43
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	09 Oct 2020 15:45:34
	(b) (4)	

US3222554

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered '28 Jan 2021'	douglas winter (b) (4)	03 Mar 2021 17:26:56
	(b) (4)	

US3222554

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'ABD/PELVIS W/CONT-CT SCAN'	douglas winter (b) (4)	03 Mar 2021 17:27:16
reason for change: Data Entry Error	(b) (4)	
User entered 'ABD/PELIC W/CONT-CT SCAN'	douglas winter (b) (4)	03 Mar 2021 17:26:56
	(b) (4)	

US3222554

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered 'Adverse Event (AE)'	douglas winter (b) (4)	03 Mar 2021 17:26:56
	(b) (4)	

US3222554

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:57

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
	(b) (4)	
User entered empty.	douglas winter (b) (4)	03 Mar 2021 17:26:56
	(b) (4)	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:07
Un-reviewed for Safety.		19 Apr 2021 20:35:03
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'USA-US104-2021-MRNA-1273-P301000006'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
User closed query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:12
Query 'Please update Investigator and Address to reflect Dr. Rankin. ' answered with 'corrected' (Site from CRA).		12 Apr 2021 14:39:02
Un-reviewed for Safety.		08 Apr 2021 16:28:24
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Bruce' reason for change: Data Entry Error		08 Apr 2021 16:27:55
User opened query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA). DataPoint Un-verified.		30 Mar 2021 17:06:57
DataPoint Verified.		30 Mar 2021 17:06:26
User signature succeeded.	Bruce Rankin (b) (4)	30 Mar 2021 17:06:22
Reviewed for Safety.	(b) (4)	22 Feb 2021 20:41:53
User entered 'Teresa'	(b) (4), (b) (6)	02 Feb 2021 17:20:19
	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:04
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Rankin' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:28
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered 'Becker'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Un-verified.	System	19 Apr 2021 20:02:38
User entered '860 Peachwood Ave'	System	19 Apr 2021 20:02:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:06
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '860 Peachwood Drive' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:29
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered '6550 Mapleridge Street'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:07
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Deland' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:30
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered 'Houston'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:09
User entered empty.		08 Apr 2021 16:27:55

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:11
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '32720' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:32
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered '77081'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'US'	(b) (4) System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 20:35:23
User entered '3'	System	19 Apr 2021 20:02:38
User entered '2'	System	04 Mar 2021 16:27:35
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
	(b) (4)	
User entered '1'	System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:07
Un-reviewed for Safety.		19 Apr 2021 20:35:03
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'USA-US104-2021-MRNA-1273-P301000006'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
User closed query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:39:12
DataPoint Verified.		12 Apr 2021 14:39:02
Query 'Please update Investigator and Address to reflect Dr. Rankin. ' answered with 'corrected' (Site from CRA).		08 Apr 2021 16:28:24
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Bruce' reason for change: Data Entry Error		08 Apr 2021 16:27:55
User opened query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA).		30 Mar 2021 17:06:57
DataPoint Un-verified.		30 Mar 2021 17:06:26
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered 'Teresa'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:04
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:27:55
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:27:55
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:27:55
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:28
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Becker'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Un-verified.	System	19 Apr 2021 20:02:38
User entered '860 Peachwood Ave'	System	19 Apr 2021 20:02:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:06
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '860 Peachwood Drive' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:29
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered '6550 Mapleridge Street'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:07
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Deland' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:30
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered 'Houston'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:09
User entered empty.		08 Apr 2021 16:27:55

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:11
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '32720' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:32
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered '77081'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'US'	(b) (4) System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 20:35:23
User entered '3'	System	19 Apr 2021 20:02:38
User entered '2'	System	04 Mar 2021 16:27:35
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
	(b) (4)	
User entered '1'	System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:06:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered '02/Feb/2021 12:20'	(b) (4) System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:06:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'l'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:07
Un-reviewed for Safety.		19 Apr 2021 20:35:03
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'USA-US104-2021-MRNA-1273-P301000006'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
User closed query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:39:12
DataPoint Verified.		12 Apr 2021 14:39:02
Query 'Please update Investigator and Address to reflect Dr. Rankin. ' answered with 'corrected' (Site from CRA).		08 Apr 2021 16:28:24
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Bruce' reason for change: Data Entry Error		08 Apr 2021 16:27:55
User opened query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA).		30 Mar 2021 17:06:57
DataPoint Un-verified.		30 Mar 2021 17:06:26
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered 'Teresa'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:04
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Rankin' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:28
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Becker'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Un-verified.	System	19 Apr 2021 20:02:38
User entered '860 Peachwood Ave'	System	19 Apr 2021 20:02:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:06
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '860 Peachwood Drive' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:29
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered '6550 Mapleridge Street'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:07
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Deland' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:30
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Houston'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:09
User entered empty.		08 Apr 2021 16:27:55

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:11
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '32720' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:32
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered '77081'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'US'	(b) (4) System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 20:35:23
User entered '3'	System	19 Apr 2021 20:02:38
User entered '2'	System	04 Mar 2021 16:27:35
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
	(b) (4)	
User entered '1'	System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:06:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered '04/Mar/2021 11:27'	(b) (4) System	04 Mar 2021 16:27:35

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:06:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:27:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:27:35

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:07
Un-reviewed for Safety.		19 Apr 2021 20:35:03
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'USA-US104-2021-MRNA-1273-P301000006'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
User closed query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:39:12
DataPoint Verified.		12 Apr 2021 14:39:02
Query 'Please update Investigator and Address to reflect Dr. Rankin. ' answered with 'corrected' (Site from CRA).		08 Apr 2021 16:28:24
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Bruce' reason for change: Data Entry Error		08 Apr 2021 16:27:55
User opened query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA).		30 Mar 2021 17:06:57
DataPoint Un-verified.		30 Mar 2021 17:06:26
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered 'Teresa'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:04
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Rankin' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:28
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered 'Becker'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Un-verified.	System	19 Apr 2021 20:02:38
User entered '860 Peachwood Ave'	System	19 Apr 2021 20:02:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:06
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '860 Peachwood Drive' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:29
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered '6550 Mapleridge Street'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:07
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Deland' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:30
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Houston'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:09
User entered empty.		08 Apr 2021 16:27:55

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:11
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '32720' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:32
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered '77081'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'US'	(b) (4) System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 20:35:23
User entered '3'	System	19 Apr 2021 20:02:38
User entered '2'	System	04 Mar 2021 16:27:35
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
	(b) (4)	
User entered '1'	System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:06:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '19/Apr/2021 16:02'	(b) (4) System	19 Apr 2021 20:02:38

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:06:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
User entered 'I'		19 Apr 2021 20:02:38

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:07
Un-reviewed for Safety.		19 Apr 2021 20:35:03
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'USA-US104-2021-MRNA-1273-P301000006'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Yes (Y)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'No (N)'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
User closed query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:12
Query 'Please update Investigator and Address to reflect Dr. Rankin. ' answered with 'corrected' (Site from CRA).		12 Apr 2021 14:39:02
Un-reviewed for Safety.		08 Apr 2021 16:28:24
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Bruce' reason for change: Data Entry Error		08 Apr 2021 16:27:55
User opened query 'Please update Investigator and Address to reflect Dr. Rankin. ' (Site from CRA). DataPoint Un-verified.		30 Mar 2021 17:06:57
DataPoint Verified.		30 Mar 2021 17:06:26
User signature succeeded.	Bruce Rankin (b) (4)	30 Mar 2021 17:06:22
Reviewed for Safety.	(b) (4)	22 Feb 2021 20:41:53
User entered 'Teresa'	(b) (4), (b) (6)	02 Feb 2021 17:20:19
	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	19 Apr 2021 20:35:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:04
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Rankin' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:28
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	02 Feb 2021 17:20:19
User entered 'Becker'	(b) (4), (b) (6)	02 Feb 2021 17:20:04
	System	

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Un-verified.	System	19 Apr 2021 20:02:38
User entered '860 Peachwood Ave'	System	19 Apr 2021 20:02:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:39:06
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '860 Peachwood Drive' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:29
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered '6550 Mapleridge Street'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:07
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered 'Deland' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:30
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered 'Houston'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:09
User entered empty.		08 Apr 2021 16:27:55

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		12 Apr 2021 14:39:11
Un-reviewed for Safety.		08 Apr 2021 16:27:55
Signature has been broken.		08 Apr 2021 16:27:55
User entered '32720' reason for change: Data Entry Error		08 Apr 2021 16:27:55
DataPoint Un-verified.		30 Mar 2021 17:06:32
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:20:19
User entered '77081'	System	02 Feb 2021 17:20:04

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:35:01
DataPoint Verified.		30 Mar 2021 17:06:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
User entered 'US'	(b) (4) System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 20:35:23
User entered '3'	System	19 Apr 2021 20:02:38
User entered '2'	System	04 Mar 2021 16:27:35
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 20:41:53
	(b) (4)	
User entered '1'	System	02 Feb 2021 17:20:26

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:06:57

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered '19/Apr/2021 16:35'	(b) (4) System	19 Apr 2021 20:35:23

US3222554

Folder: SAE USA-US104-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:06:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 15:04:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:35:23